

# **RESEARCH PROTOCOL**

Title: Effectiveness of Virtual Reality Gaming Therapy Versus CI Therapy for Upper Extremity Rehabilitation

Clinicaltrials.gov NCT02631850

Document Date: May 3, 2017

Revised to include this cover page on August 18, 2021

## Contents

Coverletter.....	4
Dates of IRB Approvals and Associated Modifications: .....	4
Research Protocol.....	5
Consent Form .....	14
Adverse event recording form.....	20
Withdrawal Form .....	22
Recruitment materials .....	23
Phone Screening.....	27
RCT In-Person Participant Screening Form.....	29
Treatment materials – CI therapy.....	33
Checklist.....	33
Description of Therapy.....	37
Treatment Contract.....	38
Caregiver Contract .....	39
Home Achievement Record of Treatment Contract.....	40
Potential Home Practice Tasks.....	43
Home Practice Recording Log .....	52
Motor Activity Log Treatment Record .....	53
Motor Practice Recording Forms .....	54
Video Recording Log.....	57
Treatment materials – Gaming CI therapy Groups .....	58
Checklist Self-Gaming .....	58
Checklist Tele-Gaming .....	60
Description of Therapy.....	63
Treatment Contract.....	64
Caregiver Contract .....	65
Home Achievement Record of Treatment Contract.....	66
In-clinic Treatment Schedule .....	69
In-home game play schedule.....	70
Home Practice Recording Log is the same form as for the CI therapy group. ....	71
Game Gestures Key .....	72
Video Recording Log Self-Gaming: .....	74

Video Recording Log Tele-Gaming:.....	75
MAL in Follow-up Recording Form for Tele-Gaming Group:.....	76
Limb Activation Instructions (Pebble Watch):.....	77
Pebble Watch Log: .....	78
Treatment Materials – Usual Care .....	79
Traditional Rehabilitation Protocol.....	79
Traditional Therapy Checklist (Group 4).....	83
Video Recording Log .....	84
Usual Care Treatment Log .....	85
Assessment Measures.....	86
Treatment Received Form.....	92
Demographic Information .....	97
Therapist Observations to be collected on LAST day of treatment: .....	98

## Coverletter

The IRB-approved protocol was written for review by a lay audience. As such, it does not contain as much detail about the statistical analysis plan and other more technical details of the trial. The detailed study protocol, including statistical analysis plan, was published in BMC Neurology:

Gauthier, L. V., Kane, C., Borstad, A., Strahl, N., Uswatte, G., Taub, E., ... & Mark, V. (2017). Video Game Rehabilitation for Outpatient Stroke (VIGoROUS): protocol for a multi-center comparative effectiveness trial of in-home gamified constraint-induced movement therapy for rehabilitation of chronic upper extremity hemiparesis. *BMC neurology*, 17(1), 1-18.

This trial reflects one aim (Aim 4) within a larger program of research covered in the IRB application that began with development of the gaming system (Aims 1-2) and initial pilot testing of the gaming self-management approach (Aim 3). Only Aim 4 of the IRB application relates to the multi-site randomized controlled trial. Only the sections of the IRB pertaining to the randomized controlled trial are included here to avoid confusion. Study-related treatment materials that were open-sourced to an internet repository referenced within the published protocol are also included within this document.

The trial is registered at [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02631850) NCT02631850.

## Dates of IRB Approvals and Associated Modifications:

11/23/15 – IRB Amendment Approved for Aim 4 of the Study (the Multi-site Randomized Controlled trial presented in this original journal article).

9/20/16 – New recruitment flyers were added based on stakeholder revisions to the text on the original recruitment materials and design edits by The Ohio State University's (OSU) Center for Clinical and Translational Sciences.

3/9/17 – Non-significant risk device determination was added for the Recovery Rapids gaming system and the smart-watch app to provide feedback on amount of daily arm use.

5/3/17 – A qualitative survey on experience with CI therapy, especially the behavioral techniques, was added to the post-treatment testing session if the participant consented to an additional interview with the research assistant. This measure was only administered to a small subset of participants at OSU.

# Research Protocol

**Title** A low-cost virtual reality gaming platform for neurorehabilitation of hemiparesis

## I. Objectives

A relatively recent rehabilitation strategy, constraint-induced movement therapy (CI therapy), produces substantial recovery of arm function. Although viewed as the “gold standard” intervention for arm hemiparesis by many practitioners, CI therapy is unavailable to most patients due to its cost, travel/scheduling demands, and dearth of trained providers. For example, CI therapy is typically not covered by insurance and the 30+ hours of assessment and physical training usually cost patients upwards of \$6,000. Most patients are required to travel long distances, often out of state, multiple times a week to seek this care. Many of these patients have only intermittent access to transportation and/or limited financial means to travel. Thus, patient dissatisfaction with not receiving adequate rehabilitation is high and there is a fundamental need for low-cost, accessible interventions with the potential to improve arm function. The objective of this project is to test, in collaboration with the patients it is designed to serve, a home-based, computer-gaming version of CI therapy that will provide high-quality rehabilitation to patients who are typically not afforded access to effective therapies.

**Aim 4:** A larger randomized controlled trial will be conducted, comparing the effectiveness of a 3D video game delivery model of CI therapy versus traditional clinic-based CI therapy and standard care.

Our team’s long-term goal is to use newly available technological innovations to increase access to motor rehabilitation while reducing cost of care. In keeping with our overall program of research, the proposed work aims to establish the comparative effectiveness of a three-dimensional (3D) video game delivery model of CI therapy versus traditional clinic-based CI therapy and standard care. Data from this trial will enable individuals with hemiparesis to evaluate whether a home-based video game therapy has the potential to meet their rehabilitation goals compared to clinic-based CI therapy and traditional rehabilitation approaches. We propose a multisite randomized controlled trial with two subaims:

*Aim 4a: To determine the comparative effectiveness of a therapist-as-consultant video-game delivery model of CI therapy.* The Motor Activity Log (a reliable and valid measure of arm use for daily activities) and the Wolf Motor Function Test (measures time required to perform functional movements) will serve as primary motor outcome measures.

*Aim 4b: To examine individual factors that may differentially influence response to one treatment versus another.* Initial motor ability, cognition, somatosensation, intensity of both in-clinic and home-based motor practice, treatment compliance, age, and chronicity will be examined as potential moderators of motor outcome.

## II. Background and Rationale

CI therapy is a highly efficacious motor rehabilitation therapy for stroke or hemiparesis of other etiologies. It has been shown to substantially increase the amount of use of an affected upper extremity<sup>5-7</sup> and to promote structural and functional brain plasticity.<sup>8-12</sup> CI therapy is distinctive from traditional rehabilitation in several ways. 1) It involves a highly compressed and intensive training schedule (training of the more impaired arm on functional tasks for 3 hours daily for 10 consecutive weekdays). 2) CI therapy incorporates restraint of the less-impaired (i.e., “good”) hand for a target 90% of waking hours. Restraint is delivered via a padded mitt that discourages the patient to engage in compensatory behavior with the less affected arm<sup>13,14</sup> and teaches the patient to use the more-affected (i.e., “bad”) arm for daily activities. 3) CI therapy utilizes a number of behavioral techniques termed the “transfer package.” The transfer package was designed to facilitate transfer of therapeutic

gains to real world activities, thereby enabling the patient to overcome the conditioned suppression of movement (e.g., learned nonuse) characteristic of chronic hemiparesis.<sup>13,14</sup> Transfer package techniques include daily monitoring of life situation use of the more affected arm via daily administration of the Motor Activity Log (a structured interview that monitors use of the more-impaired arm for 28 daily activities), providing feedback on patient progress, and problem-solving with the therapist to overcome perceived barriers to using the extremity.

The transfer package is perhaps the most revolutionary element of CI therapy in that it leverages psychological theory to induce behavioral change. Patient gains in real-world arm use are reduced by approximately 67% when it is omitted from the CI therapy protocol.<sup>12</sup> Furthermore, patients fail to demonstrate the brain reorganization that is typical of CI therapy in the absence of the transfer package.<sup>12</sup> Behavior-monitoring and problem-solving elements (strongly emphasized by the transfer package) are present in most empirically-validated psychological interventions that target behavior change and their importance to the field of physical rehabilitation is becoming increasingly apparent. Traditional approaches to motor rehabilitation that heavily emphasize strength, speed, or “normalcy” of movement (i.e., motor training only), and do not incorporate elements of the transfer package, often yield motor gains that do not translate into improved function for the patient (i.e., the patient still operates unimanually at home). Through use of the transfer package, CI therapy patients regain their ability to use both arms for daily tasks, enabling them to retain motor gains over time.

Despite its effectiveness, CI therapy is available to less than 1% of the estimated 1.2 million chronic stroke survivors who could benefit from it. Common barriers to access include dearth of trained providers, cost, insurance caps, and travel/scheduling demands. Although in its infancy, telemedicine is an emerging field with substantial promise to produce exceptional interventions at low cost that can be widely distributed. Most studies to date have found that virtual reality interventions are at least as effective as their low-technology counterparts.<sup>1-4</sup> To deliver CI therapy to underserved individuals, a novel patient-centered approach to rehabilitation was developed that utilizes newly developed, inexpensive, and commercially available gaming technology (Microsoft Kinect). Initial evidence from a pilot trial of this system suggests that improvements in motor speed, an outcome of prime importance to stroke survivors, are approximately equivalent to those reported in the traditional CI therapy literature. Qualitative data reveal that the technology is accepted irrespective of age, technological expertise, ethnicity, or cultural background. A randomized clinical trial is now required to provide reliable (level 1) evidence of the effectiveness of this novel model of CI therapy delivery.

### III. Procedures

#### **Aim 4. To compare the effectiveness of a 3D video game delivery model of CI therapy versus traditional clinic-based CI therapy and standard care in a randomized controlled trial.**

##### **Administration**

OSU will serve as the lead site for a multi-site trial. Communication between sites will occur through quarterly phone calls (and more frequently if needed) between OSU PI and the PI of the sites. In-person site visits will also occur at the beginning of the project and again after sites have obtained ~25% enrollment. Video-based site visits may replace in-person site visits in some instances as appropriate. Site trainings will occur at each site and will include procedures necessary for maintaining data security and participant privacy (e.g., procedures for uploading study testing forms to secure REDCap database at OSU).

The central database for the project will be maintained at OSU (REDCap). All records for the study will be scanned in by each site and uploaded to REDCap. Adherence to study treatment and testing protocols will be checked by a blind rater at OSU whose job is to randomly review video-taped treatment and testing sessions. Significant deviations from protocol will be addressed by retraining personnel or termination (if the problems

persist). Video data (e.g., see above) will be transferred to OSU from the other sites via USPS on encrypted storage drives.

Unanticipated problems (from all sites) will be reported to the OSU PI, OSU’s central IRB, as well as to the PIs of individual sites. To avoid a potentially large volume of reports of external adverse events, the HHS Office of Human Research Protections (OHRP) has released guidance urging that individual adverse events should only be reported to investigators at all institutions when a determination has been made that the events meet the criteria for an unanticipated problem. OHRP recommends that any distributed reports include: (1) a clear explanation of why the adverse event or series of adverse events has been determined to be an unanticipated problem; and (2) a description of any proposed protocol changes or other corrective actions to be taken by the investigators in response to the unanticipated problem. Adverse event reporting for the proposed research will follow this model.

An initial analysis of data will be conducted at OSU after 50% total recruitment. These interim findings will be shared with other site PIs by the OSU PI. Decisions to modify the protocol based on interim findings will be made jointly between all the sites to ensure protocol consistency. Interim findings that may influence protocol safety and willingness to participate will be reported to the IRBs at each institution by the PIs at each institution.

**Research Design**

Individuals with chronic stroke will be randomized to one of four different interventions: (1) traditional clinic-based CI therapy (35 therapist/client contact hours), (2) therapist-as-consultant virtual reality CI therapy (5 therapist/client contact hours in the clinic and 15 hours of independent game play at home), (3) therapist-as-consultant virtual reality CI therapy with additional therapist contact via telerehabilitation (5 therapist/client contact hours in the clinic, 6 additional brief teleconference sessions, and 15 hours of independent game play in the home), and (4) 5 hours of standard occupational therapy. The clinic-based CI therapy arm is the "gold standard" against which gaming therapy is compared (group 1 versus group 2 and group 3). The comparison to standard care (group 2 versus group 4) will demonstrate whether game-based treatment between therapy sessions enhances motor outcomes. The comparison between groups 2 and group 3 will determine the extent to which additional therapist monitoring via video conference improves treatment response of a home-based intervention. Motor function (Wolf Motor Function Test) and daily use of the more affected hand (accelerometry) will be measured prior to treatment, after treatment, and 6 months later.

**Sample & Inclusion/Exclusion Criteria**

Relatively relaxed enrollment criteria will be employed to include a representative sample of patients with upper extremity motor impairment. Patients who have experienced a stroke (of any etiology) resulting in hemiparesis at least six months prior, have preserved ability to comprehend and participate in basic elements of the therapy, who have corrected vision of at least 20/70 (individuals with low vision would have difficulty participating in the gaming intervention), who are not currently participating in other experimental upper extremity trials, who are not currently engaged in other outpatient rehabilitation for their upper extremity, and who have not received Botox within the last 3 months (confound) will be eligible to participate. Eligible participants will receive an in-person screening to ensure their ability to safely engage in rehabilitation. Patients deemed too frail to undergo intensive rehabilitation or those with serious, uncontrolled medical problems will be excluded (e.g., debilitating pain). The recruited sample will represent approximately 50% of individuals with hemiparesis. Participants will be stratified by severity of impairment (see table below) and separately randomized to reduce potential baseline inequality between groups.

<b>Severity of Impairment</b>	<b>Shoulder</b>	<b>Elbow</b>	<b>Wrist</b>	<b>Fingers</b>	<b>Thumb</b>
<b>Mild-moderate</b>	Flexion $\geq 45^\circ$ and Abduction $\geq 45^\circ$	Extension $\geq 20^\circ$ from a $90^\circ$ flexed starting position	Extension $\geq 20^\circ$ from fully flexed starting position	Extension of all MCP and (PIP or DIP) joints $\geq 10^\circ$	Extension or abduction of thumb $\geq 10^\circ$
<b>Moderate</b>	Flexion $\geq 45^\circ$ and	Extension $\geq 20^\circ$	Extension $\geq 10^\circ$	Extension MCP	Extension or

	Abduction $\geq 45^\circ$	from a $90^\circ$ flexed starting position	from fully flexed starting position	and (PIP or DIP) joints of at least 2 fingers $\geq 10^\circ$	abduction of thumb $\geq 10^\circ$
--	---------------------------	--	-------------------------------------	---	------------------------------------

### Measurement/Instrumentation

Primary measures:

- Motor Activity Log
- Wolf Motor Function Test

Secondary measures:

- bilateral activity monitors (accelerometers)
- Patient Health Questionnaire (PHQ-9)
- Touch Test Monofilaments
- Neuro-QOL
- 9-Hole Peg Test
- Brief Kinesthesia Test
- Kinematic Analysis (performed on skeletal Kinect data collected during game play)
- Montreal Cognitive Assessment (MoCA)

Measures will be administered within a week prior to beginning treatment, in the week following treatment, and at 6-month follow-up ( $\pm 1$  month). A rehabilitation professional blinded to treatment condition will perform the testing. Reliability of the blinded assessors will be monitored by videotaped assessments reviewed by independent raters.

Additional quality metrics that could create apparent differences in effectiveness in clinical populations will also be measured. After completion of participation, we will survey participants to collect qualitative feedback regarding their experiences with the treatment. Participants will be asked about which therapy condition (traditional CI therapy, gaming CI therapy, standard therapy) they would have preferred under ideal (i.e., cost and transportation are not an issue) and realistic (i.e., their current resources are a consideration) conditions. Differential adherence will also be examined by the proportion of therapy sessions attended, hours of mitt use objectively quantified by a sensor in the mitt, hours of game play, and self-reported compliance with home practice.

Outcome measure	Addresses	Pre	Post	6mo
Motor Activity Log	Nonuse for daily activities	x	x	x
WMFT	Motor speed/function	x	x	x
Grip strength of WMFT <sup>99</sup>	Weakness	x	x	x
Kinematics	Weakness, range of motion, motor control, ataxia, poor precision, speed, hypertonicity	x	x	x
Neuro-QOL	Quality of Life	x	x	x
Activity monitoring	Nonuse for daily activities	x	x	x
Brief Kinesthesia Test	Sensory proprioception	x	x	x
Touch Test Monofilaments	Tactile loss	x	x	x
Montreal Cognitive Assessment (MoCA)	Cognitive screen	x		

Survey			x	
--------	--	--	---	--

## Recruitment

Participants will be primarily recruited through mining the electronic medical records (e.g., through Information Warehouse at Ohio State University Wexner Medical Center and the Quality and Patient Safety Department at OhioHealth) to generate a list of potentially eligible participants [not deceased individuals with an ICD-9 diagnostic code of 438.2 (chronic hemiparesis) or 438.3 (chronic monoplegia of upper limb) or ICD-10 equivalent]. After obtaining approval to contact potential participants from their treating providers, they will be informed of the study through a mailing. Interested participants will contact the site coordinator to be screened for participation. Members of the health system who use a system such as OSU MyChart will also be recruited via targeted messaging (to those who may meet recruitment criteria based on the diagnostic codes above). A message would appear in their MyChart account, telling them very briefly about the study and asking them if they are interested in learning more. If they indicate on MyChart that they are interested in being approached about research participation, the PI will receive a message to follow up with the potential participant. Participants will also be recruited from community stroke groups, from internet forums, via study flyers posted within the community, from the general clientele of the outpatient clinics, through internet advertising (e.g., Facebook), through direct mailing (e.g., USPS Direct) and through the use of Research Match. Internet advertising, direct mailing, and study flyers posted within the community will be used to specifically target rural dwelling participants.

## Detailed Study Procedures

The current proposal aims to conduct a multi-site randomized controlled trial comparing virtual-reality gaming delivery of CI therapy with (1) traditional clinic-based CI therapy *of equal total duration* and (2) a control group *equating the dose of in-person therapy*. Individuals with chronic stroke will be randomized to one of four different interventions: (1) traditional clinic-based CI therapy (35 therapist/client contact hours), (2) therapist-as-consultant virtual reality CI therapy (5 therapist/client contact hours in the clinic and 15 hours of independent game play at home), (3) therapist-as-consultant virtual reality CI therapy with additional therapist contact via telerehabilitation (5 therapist/client contact hours in the clinic, 6 brief contacts via teleconference, and 15 hours of independent game play in the home), and (4) 5 hours of standard occupational therapy. After 6-month follow-up, individuals assigned to standard OT/PT will cross over to a modified gaming therapy condition (a stand-alone application of the rehabilitation game without additional therapist contact). This crossover design is ethically responsible and will enable the team to test the feasibility and initial efficacy of a completely stand-alone implementation of the game, as well as to determine the effect of varying amounts of therapist contact on game-based rehabilitation outcomes (group 2 vs group 3 vs group 4 crossed over).

**Table: Timeline of Participation**

STUDY ARM	Pre-tx testing, week 1	THERAPY (weeks 2-4)	Post-tx testing, week 5	6 month follow-up testing	THERAPY	
CI therapy		35 face-to-face hours, 15 spent in active motor practice				
CI therapy gaming (2)		5 face-to-face hours, 15 hours in-home gaming				
CI therapy gaming (3)		5 face-to-face hours, 2.6 teleconsultation hours, 15				

		hours in-home gaming				
<b>Standard care</b>		5 face-to-face hours			15 hours in-home gaming	<b>Post-gaming testing</b>

**Group 1, Traditional CI therapy:** We will employ a 35-hour “dose” of CI therapy in the current trial. All elements of traditional CI therapy will be provided. Treatment will consist of 35 therapist/client contact hours in the clinic, over the course of 3 weeks. Delivery of the “transfer package” will occur during the other 5 hours and will include the following elements: (1) establishing a behavioral contract (in which goals for the intervention are set, the therapist secures the client’s “buy in,” a plan for increased use of the more affected upper extremity in the home setting is drafted, and a schedule of mitt use is established), (2) daily administration of the Motor Activity Log (self-assessment of weaker arm use for daily activities), (3) a daily diary of new activities attempted at home is reviewed, and (4) problem-solving to overcome barriers to use of the more affected upper extremity is conducted. In addition, the client will agree to wear a padded restraint mitt on the less affected hand for the majority of waking hours to encourage use of the weaker hand for daily activities. The restraint mitt is equipped with a sensor to provide the participant with feedback on how long he/she has worn the mitt. Finally, the participant will agree to 30 minutes per day of individualized task-practice outside the clinic (in addition to training in the clinic) focused on functional activities catered towards accomplishing the person’s therapeutic goals.

**Group 2, Gaming CI therapy.** This intervention is designed such that physical/occupational therapists manage patients in a consultative role, thus allowing more patients to be served. 5 therapist/client contact hours will occur in the clinic on approximate treatment days 1, 3, 6, and 11 and will focus on treatment elements that cannot be readily addressed through the game (e.g., transfer package with guided problem-solving). The first session with the therapist (2 hours) will involve establishing the behavioral contract, reviewing the Motor Activity Log (from pre-test) with guided problem-solving, and customizing the game to the participant. Thereafter, sessions will focus on review of progress with the home program, modifying game customization as needed, and on treatment elements that cannot be readily addressed through the game (e.g., guided problem-solving portion of the transfer package with ADL practice as needed, establishing home skill assignments collaboratively). Matching the CI therapy delivery schedule, 15 hours of progressive massed motor practice will occur through in-home video game play over 3 weeks. Participants will play the game during times of their choosing. The proposed delivery system thus allows patients access to rehabilitation between episodes of care provided by therapists. This distribution of activities amounts to the same amount of active motor practice as CI therapy (15 hours) and 5 hours of “transfer package” activities, equivalent to that of traditional CI therapy. In lieu of the mitt, the participant will wear an activity monitor biofeedback device for the majority of waking hours. As with traditional CI therapy, the client will agree to an additional 30 minutes per day of individualized task-practice.

Game play is driven by the user’s movements that are captured with the Microsoft Kinect/Xbox One camera (cost of less than \$500). The Microsoft Kinect is a controller-free motion capture device with built-in video cameras and 3D depth sensors to capture and record participant motion. An avatar then replicates the participant’s movements in the gaming environment. The “controller-free” environment makes the Kinect system user-friendly for patients who are not accustomed to technology and provides monitoring of the user’s actual movements. Its intuitive design is thus ideal for rehabilitation applications in which individuals may have little comfort with technology or substantial cognitive impairment. It is well suited for rehabilitation because it requires no devices or wires to be attached to the person and can capture fairly accurate representations of coordinated motor patterns. Components of the system include a computer with PC Kinect (or Xbox One integrated gaming console), an armless chair where the patient can safely sit to perform the game, and a television display.

The movements required to navigate the game environment were designed to be intuitive (based on input from our stakeholders), while also focusing on motor routines known to be helpful for recovery of hemiparesis (e.g., extension, supination). Various therapeutic gestures (e.g., how the hand moves relative to the shoulder and elbow) drive game play. Therapeutic gestures were coded with a focus on minimizing reinforcement of compensatory movement patterns and have been validated on more than 40 individuals with hemiparesis.

The game environment (also developed with input from stakeholders) consists of a quest down a river canyon that winds through various terrains (mountains, tropical, dessert, and underground caves). The user must paddle a kayak through this terrain, collecting hidden treasure, fishing for food, capturing essential supplies that are parachuted down from above, gathering food, and pulling objects from the river. The user must remain vigilant; bats and otherworldly creatures can attack in the caves, river rapids can crash the kayak into the rocks, and low hanging obstacles need to be avoided or the avatar will develop a headache.

To promote the extended game-play required for CI therapy and enable customization to the user, the game utilizes procedural content generation (mathematical algorithms that generate game content based on therapist specifications and continuously change game scenery “on the fly”). The CI therapy principal of shaping (progressively increasing task difficulty as a person improves) is automated through the game. In just one example, bats flock around the avatar’s head to encourage the user to raise the paretic hand above the shoulder and across the body. To disperse the bats, the player must “swat” the bats out of the way with the paretic hand. An introductory level of this gesture may require only that the paretic hand reaches above the level of the navel. As a person’s range of motion improves, the game advances the player to reach across midline in addition to above shoulder level and, eventually, to higher above the shoulder and further across the body.

As with traditional CI therapy, the game also incorporates some elements of the “transfer package” that promote transfer of motor gains to daily activities. One such element is the Motor Activity Log (MAL). It is a highly structured self-monitoring interview that asks patients how effectively their more affected arm performed activities of daily living over the past 48 hours. Daily administration of the MAL is believed to be the most important element of the “transfer package” because it provides self-monitoring of arm use and problem-solving regarding how the client can incorporate use of the more affected upper extremity into his/her daily routine. To automate this self-assessment, the user matches his/her performance to a video of a stroke participant performing each task. If participants answers that he/she did not perform an activity, a problem-solving module appears in which the user must select from various strategies that may aid him/her in performing the task (strategies were provided by therapist stakeholders).

**Group 3, Gaming CI therapy with additional contact via video conference.** This group will receive treatment that is identical to Group 2, but will receive an additional 6 brief video conference consultations throughout the treatment period so that this group receives the same number of therapist encounters as the CI therapy group.

**Group 4, Traditional occupational/physical therapy focusing on the upper extremity.** Five therapist/client contact hours will occur on approximate treatment days 1, 3, 6, and 11 (same schedule as gaming CI therapy). The treatment protocol was developed collaboratively by therapists on our Advisory Board given the question: “What protocol would you utilize if you were only given 5 contact hours to treat a client [with mild/ moderate hemiparesis]?” Although responses differed somewhat regarding the relative amounts of time devoted to the following activities, an average protocol was constructed consisting of the following: 1-hour progressive resistance exercise to establish and progress an upper extremity home exercise program, 2 hours of neuromuscular reeducation, and 2 hours functional practice on ADLs with verbal encouragement to use the more affected upper extremity to the largest extent possible. Home practice consists of stretching exercises, designed to increase range of motion, prescribed twice daily. After completing their participation in the standard OT condition (6 months), participants will be crossed over to a CI therapy gaming only condition. This condition will be identical to that described above, excluding therapist contact throughout the intervention. Following an initial consultation with a therapist, participants

will receive a DVD explaining the intervention and guiding them through self-management. The rationale for crossing over participants in the standard occupational therapy condition is two-fold: 1) this will allow testing the efficacy of a stand-alone implementation of the game (the only feasible treatment option for participants who are unable to access a clinic), and 2) it is ethically responsible given our hypothesis that the standard OT group will show inferior outcomes compared to the groups receiving CI therapy or gamified CI therapy.

**Data handling-** The OSU CCTS Research Informatics Services Core will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners (including OSU) and the NIH National Center for Research Resources, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the CCTS Research Informatics Services Core. As part of the data dictionary development process, individual fields can be denoted as “identifiers”. When exporting a de-identified dataset, these variables are omitted. Additionally, the data export tool also allows for the shifted of dates for a limited data set export. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data and has real time validation rules (with automated data type and range checks) at the time of entry. It offers easy data manipulation with audit trails and ad hoc reporting functionality for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap is 21 CFR Part 11 capable. Currently, REDCap installations support electronic signatures by positively identifying the user through a unique username and password combination. The provisioning of accounts and user access to specific database(s) is integrated with the OSU Medical Center LDAP authentication service for studies containing protected health information (PHI), and the provisioning of access and specific user rights for all studies are managed by CCTS staff.

**Handling missing data -** We will prevent missing data through the use of checklists. These checklists will ensure that all measures are collected at each assessment session in a consistent order according to study protocol. Checklists will also minimize data loss due to technical difficulties (e.g., improper initialization of the bilateral activity monitors, dead batteries, etc.). Automated reminder calls will be sent to participants to reduce missed appointments and to remind participants to wear the activity monitors. Missed appointments will be rescheduled immediately. Testing data will be entered into a secure (and backed-up) REDCap database within 48 hours of data collection. Reasons for drop-out (and whether drop-out was therapist or participant-initiated) will be documented in detail. Loss to follow-up will be minimized by collecting multiple types of contact information and an alternate contact for the participant should he/she be unreachable.

**Data Analysis-** Missing data from participants who are *unable* to complete the protocol (e.g., due to random factors unrelated to the study protocol) will be removed from analysis via list-wise deletion. An ***intent-to-treat analysis*** will be carried out such that data from participants who *voluntarily withdraw* from treatment or are unable to tolerate the treatment protocol will be included; the mixed effects model planned for analysis is purely likelihood-based and can make use of all of the data available with no necessary modifications for differing numbers of subjects at each time point. Therapy-induced changes in motor ability (primary outcome measures of accelerometry and WMFT) will be analyzed via ***mixed effects linear models***. Initially, separate models will be constructed for the two primary outcome measures. Each of these models will include treatment and time (as well as their interaction) as fixed effects and subject as a random effect. In these models, the ***interaction of treatment and time is the primary effect of interest***, since it quantifies the difference in change over time among the four treatment groups. Statistical testing will be used to determine whether individuals lost to follow-up differ from those who completed the study. Demographic measures

and initial scores on outcome variables will be compared between groups using t-tests, chi-squared tests, or their non-parametric analogues. Significant differences will be considered in interpretation of the results. Results will be reported according to the CONSORT guidelines.

## REFERENCES

- (1) Laver KE, George S, Thomas S, Deutsch JE, Crotty M. Virtual reality for stroke rehabilitation. *Cochrane Database Syst Rev*. 2011;9:CD008349.
- (2) Piron L, Turolla A, Agostini M, Zucconi C, Cortese F, Zampolini M, Zannini M, Dam M, Ventura L, Battauz M, Tonin P. Exercises for paretic upper limb after stroke: a combined virtual-reality and telemedicine approach. *J Rehabil Med*. 2009;41:1016-1102.
- (3) Henderson A, Korner-Bitensky N, Levin M. Virtual reality in stroke rehabilitation: a systematic review of its effectiveness for upper limb motor recovery. *Top Stroke Rehabil*. 2007;14:52-61.
- (4) Holden MK. Virtual environments for motor rehabilitation: review. *Cyberpsychol Behav*. 2005;8:187-211; discussion 212-9.
- (5) Taub E, Miller NE, Novack TA, Cook EW, 3rd, Fleming WC, Nepomuceno CS, Connell JS, Crago JE. Technique to improve chronic motor deficit after stroke. *Arch Phys Med Rehabil*. 1993;74:347-54.
- (6) Wolf SL, Winstein CJ, Miller JP, Taub E, Uswatte G, Morris D, Giuliani C, Light KE, Nichols-Larsen D, EXCITE Investigators. Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial. *JAMA*. 2006;296:2095-2104.
- (7) Taub E, Uswatte G, King DK, Morris D, Crago JE, Chatterjee A. A placebo-controlled trial of constraint-induced movement therapy for upper extremity after stroke. *Stroke*. 2006;37:1045-9.
- (8) Liepert J, Bauder H, Wolfgang HR, Miltner WH, Taub E, Weiller C. Treatment-induced cortical reorganization after stroke in humans. 2000;31:1210-1216.
- (9) Kopp B, Kunkel A, Muhlneckel W, Villringer K, Taub E, Flor H. Plasticity in the motor system related to therapy-induced improvement of movement after stroke. *Neuroreport*. 1999;10:807-810.
- (10) Schaechter JD, Kraft E, Hilliard TS, Dijkhuizen RM, Benner T, Finklestein SP, Rosen BR, Cramer SC. Motor recovery and cortical reorganization after constraint-induced movement therapy in stroke patients: a preliminary study. 2002;16:326-338.
- (11) Wittenberg GF, Chen R, Ishii K, Bushara KO, Taub E, Gerber LH, Hallett M, Cohen LG. Constraint-Induced therapy in stroke: magnetic-stimulation motor maps and cerebral activation. 2003;17:48-57.
- (12) Gauthier LV, Taub E, Perkins C, Ortmann M, Mark VW, Uswatte G. Remodeling the brain: plastic structural brain changes produced by different motor therapies after stroke. *Stroke*. 2008;39:1520-5.
- (13) Morris DM, Shaw SE, Mark VW, Uswatte G, Barman J, Taub E. The influence of neuropsychological characteristics on the use of CI therapy with persons with traumatic brain injury. 2006;21:131-137.
- (14) Taub E, Uswatte G, Mark VW, Morris DM. The learned nonuse phenomenon: implications for rehabilitation. *Eura Medicophys*. 2006;42:241-56.
- (15) Uswatte G, Taub E, Morris D, Light K, Thompson PA. The Motor Activity Log-28: assessing daily use of the hemiparetic arm after stroke. *Neurology*. 2006;67:1189-94.
- (16) Turnbull AP, Friesen BJ, Ramirez C. Participatory Action Research as a Model for Conducting Family Research. *JASH*. 1998;23: 178-188.
- (17) McTaggart R. Principles for Participatory Action Research *Adult Education Quarterly*. 1991;41:168-187.
- (18) Whyte W editor. *Participatory action research*. Thousand Oaks, CA, US: Sage Publications, Inc.; 1991.
- (19) Venkatesh V, Morris MG, Davis FD, and Davis GB. User Acceptance of Information Technology: Toward a Unified View. *MIS Quarterly*. 2003;27:425-478.

## Consent Form

### The Ohio State University Consent to Participate in Research

**Study Title:** A low-cost virtual reality gaming platform for neurorehabilitation of hemiparesis

**Principal Investigator:** Lynne V. Gauthier, PhD

**Sponsor:** Patient-Centered Outcomes Research Institute; Departments of Physical Medicine & Rehabilitation and Computer Science, OSU

#### Aim 4 Consent form:

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University, Ohio Health, Providence Medford Medical Center, or the University of Alabama at Birmingham. If you are a student or employee at one of these institutions, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

#### 1. **Why is this study being done?**

We are doing this study to compare how well four different therapies help people recover motor function after stroke.

#### 2. **How many people will take part in this study?**

Up to 400 people who have had a stroke will participate.

#### 3. **What will happen if I take part in this study?**

You will pick a sealed note card from an envelope. When you open the note card, it will tell you which study treatment that you will receive. The four possible treatments are:

**Group 1: Traditional Constraint-Induced Movement Therapy (CIT)** involves 35 hours of therapy in the clinic within 3 weeks. During these 3 weeks, you will wear a padded mitt on your stronger hand. The purpose of the mitt is to remind you to do daily activities with your weaker hand. You will also complete a number of tasks to help you to carry-over the gains that you make in the clinic to daily life. These include practicing motor activities at home (e.g., folding laundry) for 30 minutes per day, signing a contract agreeing to wear the padded mitt and to practice using your weaker arm, answering a daily questionnaire about your arm use, and problem-solving with a therapist to overcome challenges to using your weaker arm.

OR

**Group 2: The rehabilitation game with 5 hours therapist contact** involves 15 hours of arm and hand therapy over 3 weeks in your own home by playing a video game. The game is easy to learn and involves moving your weaker arm and hand to control your character on the screen. No previous experience with video games is needed to learn the game. The game will also ask you how often you use your arm for different daily activities and will help you to problem-solve ways to use your weaker arm more often. During the three-week period of therapy, you will wear a smart watch for the majority of waking hours. The purpose of the watch is to remind you to practice daily activities with the weaker hand by alerting you when your arm is inactive. You will also complete a number of tasks to help you to carry-over the gains that you make in the clinic to daily life. These include practicing motor activities at home (e.g., folding laundry) for 30 minutes per day, signing a contract agreeing to practice everyday activities with your weaker arm, answering a daily questionnaire about your arm use, and problem-solving with your therapist to overcome challenges to using your weaker arm. You will meet face-to-face with your therapist 4 times, for a total of 5 hours. The purpose of these sessions will be to personalize the game to you and to teach you to use your weaker arm to perform daily tasks more effectively. On the last day of treatment you will fill out a brief survey regarding your experience and future uses of the gaming system.

OR

**Group 3: The rehabilitation game with 5 hours face-to-face therapist contact and additional therapist contact via videoconference.** This treatment is the same as Group 2, but an additional 2.6 hours of video contact with your therapist is added. The video contact will occur in your home (similar to a Skype call). During these video sessions, your therapist will ask you about your progress and will problem-solve through any challenges to using your weaker arm for daily activities.

OR

**Group 4: Occupational therapy.** You will meet with a therapist 4 times in the clinic for a total of 5 hours over a three-week period. The therapist will do stretching and movement exercises

with you. You will also do exercises at home every day. After 6-month follow-up, you will receive the in-home game to play.

Regardless of which treatment group you are assigned to, you will receive a lot of therapy (about 35 hours). You will receive motor and cognitive testing before you begin treatment, after treatment, and after 6-months. Each testing session will take no longer than 3 hours. Testing and therapy sessions will be video-taped. Testing sessions will involve moving your stronger and weaker arms, detecting touch sensation, and answering questions about your mood, thinking, and quality of life. In some cases, some measures may be administered over the phone. During research visits to The Ohio State University Medical Center, you may be asked to perform some tests of movement coordination. Finally, you will be asked to wear activity tracker bands during the study period and for two days surrounding each testing period to estimate how frequently you move your arms.

We will ask for your permission to contact the people with whom you live (or others who know you well). This is routine clinical care that will give us a second opinion as to how you are doing at home and how to personalize the intervention for you. It will also allow us to teach the therapy to people who know you well. We will not obtain information from family, friends, or caregivers without your permission and will not share your personal health information with them.

#### **4. How long will I be in the study?**

If you are in Group 1, you will spend 44 hours of your time over the first 4 weeks of the study. If you are in group 2, you will spend 24 hours of your time over the first 4 weeks of the study. If you are in group 3, you will spend 26 hours of your time over the first 4 weeks of the study. If you are in Group 4, you will spend 14 hours of your time over the first 4 weeks of the study. 6 months later, you will participate in a follow-up evaluation to determine how well you have maintained your motor gains over time. Group 4 will then receive gaming therapy (immediately following 6-month testing) for 15 hours and will receive a post-gaming testing session within one week after completion of the game.

#### **5. Can I stop being in the study?**

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

#### **6. What risks, side effects or discomforts can I expect from being in the study?**

Risks of participating in this study are similar to the risks of low impact exercise and other motor therapies after stroke. The assessment measures and treatments used are safe & noninvasive. Potential risks include potential fatigue and frustration during therapy and/or testing. It is possible, though unlikely, that you will experience mild stress, anxiety, or emotional distress during testing or rehabilitation.

**7. What benefits can I expect from being in the study?**

You might not receive any benefit from participating in this study. You will receive treatment for your arm weakness at no cost to you or to your insurance company. We expect that the therapies being tested in this study will benefit you, but there is the chance that the form of therapy that you are assigned to may not be effective.

**8. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits. You have the option of receiving therapy as part of your clinical care, rather than through this research study. There are currently at least two available clinical avenues for receiving CIT: 1) you could receive a more spread out form of the therapy at Morehouse Neurorehabilitation clinic at OSU; 2) you could receive the 2 week therapy program (the same training program provided in this study) at the Taub Neurorehabilitation clinic at the University of Alabama at Birmingham.

**9. Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be times where this information must be released. For example, if required by state law.

Also, the following groups may review your records:

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors

Given that this study involves a rehabilitation intervention that is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized staff involved in your medical care may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You will also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form because the study involves the use of some protected health information.

**10. What are the costs of taking part in this study?**

If you need to park at the Medical Center for an appointment, you will be responsible for the cost of parking.

**11. Will I be paid for taking part in this study?**

A travel reimbursement of \$50 per testing session will be given to each participant. Each participant who completes the in-home portions of the study protocol will receive a T-shirt and

will also be entered into a drawing for a \$25 gift card. By law, payments to participants are considered taxable income.

## **12. What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should notify the research team immediately, and you should obtain medical treatment if needed. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

## **13. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

## **14. Who can answer my questions about the study?**

For questions, concerns, or complaints about the study you may contact:

**Dr. Lynne Gauthier** 614-293-3480.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Lynne Gauthier** 614-293-3480.

## **15. Disclosures:**

The Recovery Rapids game and HandsOn app utilized in this research are in the process of being commercialized by Games that Move You, PBC to enable public access. The following investigators are cofounders of this company: Drs. Lynne Gauthier, Roger Crawfis, Alexandra Borstad, Linda Lowes, and Ryan McPherson. A conflicts management plan has been put in place to ensure the integrity and transparency of the research.

The Ohio State University owns the software used in this research, and they will receive royalties if it is sold.

### Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____	_____
Printed name of subject	Signature of subject
	_____ AM/PM
	Date and time
_____	_____
Printed name of person authorized to consent for subject (when applicable)	Signature of person authorized to consent for subject (when applicable)
	_____ AM/PM
_____	_____
Relationship to the subject	Date and time

### Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____	_____
Printed name of person obtaining consent	Signature of person obtaining consent
	_____ AM/PM
	Date and time

### Witness(es) - *May be left blank if not required by the IRB*

_____	_____
Printed name of witness	Signature of witness
	_____ AM/PM
	Date and time

_____	_____
Printed name of witness	Signature of witness
	_____ AM/PM
	Date and time

## Adverse event recording form

Return this COMPLETED FORM to your site PI as soon as possible. Site PI will notify Dr. Gauthier of the event.

Study Title: *Comparative Effectiveness of a Low-cost Virtual Reality Platform for Rehabilitation of Hemiparesis*

Participant name: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Age: \_\_\_\_\_ DOB: \_\_\_\_\_

Sex (circle one): Male Female Other

### **EVENT REPORT**

Check Type of Event:

- Study-related injury
- Participant complaint (e.g., muscle soreness)
- Policy/Procedural Violation(s) (e.g., breaking confidentiality, breaking randomization, incorrectly administering the intervention)
- Medical complication (e.g., surgery, injury outside study participation, illness)
- Psychological distress
- Other

Please describe nature of adverse event:

---

---

---

Was this event expected or unexpected? (circle one) EXPECTED UNEXPECTED

Expected event: An event will be considered expected if the nature, severity, or frequency of the event is consistent with the risk information previously described for the intervention (i.e. muscle soreness, fatigue, frustration).

Unexpected event: An event will be considered unexpected if the nature, severity, or frequency of the event is inconsistent with the risk information previously described for the intervention (e.g., a fall).

### **INVOLVEMENT OF RESEARCH PERSONNEL/RESPONSE**

Did the event occur during study treatment or testing? (circle one) YES NO

\*If yes, please continue to question #1. If no, skip to #3.

1. Describe event/complaint (Who, What, When, Where, How, Why; Include sequence of events, personnel involved, nature of injury):

---

---

---

2. Were there any witnesses to the event? If yes, please list names and contact information for each:

Witness Name: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Witness Name: \_\_\_\_\_ Phone Number: \_\_\_\_\_

3. How was the event managed at time of occurrence (if occurred in course of treatment, testing, follow-up at site)?

---

---

---

**MEDICAL FOLLOW UP**

Was Medical Attention Sought (circle one): YES NO

Date of appointment: \_\_\_\_\_

Treatment received (circle one): YES NO

First Treatment Date: \_\_\_\_\_

Treating Physician: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Does participant plan to seek medical attention? (circle one): YES NO

**REPORTING**

Incident/Complaint Documented By: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm

Site PI Notified (circle one): YES NO Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm

Dr. Gauthier Notified (circle one): YES NO Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm

Corrective Action Taken/Follow-Up (What has been done or will be done to prevent recurrence):

---

---

---

Will participant continue in study? (circle one): YES NO

If no, state reason for withdrawal: \_\_\_\_\_

Signature and Title of Person Preparing Report: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Person making Complaint: \_\_\_\_\_ Date: \_\_\_\_\_

Does this event require reporting to IRB?

- Is the event unexpected, serious, and related to the research (circle one)?: YES NO
  - Unanticipated problems that are *serious adverse events* (SAE's) should be reported to the IRB within **48 hours** of the investigator becoming aware of the event.
  - Any other unanticipated problem should be reported to the IRB within **2 weeks** of the investigator becoming aware of the problem if the problem is study-related.
  - All other events will be reported to the IRB during annual review.

\*Signing below indicates PI acknowledges responsibility for contacting appropriate IRB to report above documented event/incident/complaint.

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Withdrawal Form

Participant ID: \_\_\_\_\_

Date of Withdrawal: \_\_\_\_\_

Reason for withdrawal (circle one):    by self        by staff

Description of reason for withdrawal:

## Got poor hand or arm movement?

You may qualify for several high intensity rehabilitation sessions at NO COST, delivered by the OSU Wexner Medical Center. The Neurorecovery and Brain Imaging lab is testing the effectiveness of an in-home game-based motor intervention compared to Constraint-Induced Movement therapy and occupational therapy.



*You may qualify if:*

- You are age 18 or older
- You have experienced a stroke
- You still have trouble using your arm or hand
- You have at least a small amount of finger movement

Participation involves up to 35 hours of therapy and 3-4 sessions of motor testing. Enrolled participants will receive \$50 per testing visit & free access to study-related rehabilitation technologies.

Contact: Neurorecovery Lab at **(614) 293-6287** / [Lynne.Gauthier@osumc.edu](mailto:Lynne.Gauthier@osumc.edu)

*Interested in clinical trials but don't qualify for this one?*

Visit [ResearchMatch.org](http://ResearchMatch.org)



Wexner  
Medical  
Center

# Got poor hand or arm movement?

You may qualify for several high intensity rehabilitation sessions at NO COST, delivered by the OSU Wexner Medical Center. The Neurorecovery and Brain Imaging lab is testing the effectiveness of an in-home game-based motor intervention compared to Constraint-Induced Movement therapy and occupational therapy.



*You may qualify if:*

- You are age 18 or older
- You have experienced a stroke
- You still have trouble using your arm or hand
- You have at least a small amount of finger movement

Participation involves up to 35 hours of therapy and 3-4 sessions of motor testing. Enrolled participants will receive \$50 per testing visit & free access to study-related rehabilitation technologies.

Contact: Neurorecovery Lab at **(614) 293-6287** / [Lynne.Gauthier@osumc.edu](mailto:Lynne.Gauthier@osumc.edu)



Wexner  
Medical  
Center

Stroke Rehab Study  
Neurorecovery Lab  
(614) 293-6287

**HAVE YOU HAD A STROKE?**

**WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH STUDY  
EXAMINING A NEW MOTOR REHABILITATION GAME?**



*You may qualify if:*

- You are 18 or older
- You have had a stroke and experience weakness in your arm or hand



**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER

**HAVE YOU HAD A STROKE?**

**WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH STUDY  
EXAMINING A NEW MOTOR REHABILITATION GAME?**



*You may qualify if:*

- You are 18 or older
- You have had a stroke and experience weakness in your arm or hand



**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER

**HAVE YOU HAD A STROKE?**

**WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH STUDY  
EXAMINING A NEW MOTOR REHABILITATION GAME?**



*You may qualify if:*

- You are 18 or older
- You have had a stroke and experience weakness in your arm or hand



**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER

**HAVE YOU HAD A STROKE?**

**WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH STUDY  
EXAMINING A NEW MOTOR REHABILITATION GAME?**



*You may qualify if:*

- You are 18 or older
- You have had a stroke and experience weakness in your arm or hand



**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER



Wexner  
Medical  
Center

Date

Dear (name),

Your [insert care provider service or name here] would like you to be aware of important research studies being conducted at The Wexner Medical Center. Researchers are looking for participants who have experienced a stroke and continue to have trouble using their weaker side. The enclosed brochure[s] describe[s] studies that are now enrolling participants.

If you are interested in participating or learning more about a study, please do one of the two following actions:

1. Contact us at **XXXXXX** for more information.
2. E-mail us at XXXXXX@osumc.edu

We would like the opportunity to help you learn more about Stroke rehabilitation research at The Wexner Medical Center.

As with all research conducted at the Wexner Medical Center, your participation is voluntary. There will be no consequences to you if you choose not to participate; your medical care will not be affected by that choice. If you are eligible and choose to participate, the results of this study may help us provide better rehabilitation from stroke, and benefit individuals with stroke in the future.

Thank you in advance for considering this request

Sincerely,

## Phone Screening

### PATIENT INFORMATION:

Name: \_\_\_\_\_

Address: \_\_\_\_\_  
 \_\_\_\_\_

Phone: (\_\_\_\_) \_\_\_\_\_ DOB: \_\_\_\_\_ Date of Contact: \_\_\_\_\_

### SUPPORT PERSON INFORMATION\*

\*other than a physician, e.g., caregiver, family member, friend, nurse, etc.

Name: \_\_\_\_\_

Address: \_\_\_\_\_  
 \_\_\_\_\_

Phone: (\_\_\_\_) \_\_\_\_\_ Relationship: \_\_\_\_\_

Do we have your permission to contact this support person regarding the study?      Y      N

Do you have reliable transportation to the medical center to attend up to 4 screening/testing sessions?      Y      N

Are you willing to make up to 10 half-day trips to the medical center over the course of the study?      Y      N

### THE FOLLOWING QUESTIONS HELP US GAIN A BETTER UNDERSTANDING OF WHETHER YOU ARE LIKELY TO BENEFIT FROM CONSTRAINT-INDUCED MOVEMENT THERAPY:

Have you experienced a stroke at least 6 months ago?      Y      N

If yes, date of stroke? \_\_\_\_\_

Do you continue to experience difficulty moving your hand or arm on one side of your body?      Y      N

Which arm/hand is weaker?      R      L

Have you ever received constraint-induced movement therapy or modified constraint-induced movement therapy for your weaker arm?      Y      N

Have you previously participated in a research project to help you regain function in your weaker arm?      Y      N

If so, please describe: \_\_\_\_\_

Are you currently taking any medications to reduce tone in your weaker hand/arm (e.g., Botox)?      Y      N

Do you use any devices to help you move your weaker arm/hand?      Y      N

If so, please list: \_\_\_\_\_ How long used? \_\_\_\_\_

Do you have any surgeries planned in the next 3 months? Y N

If your weaker hand is flat on a table, can you raise it without using the shoulder or elbow? Y N

*Please answer the following questions with your weaker forearm resting on the arm of a chair, wrist bent downward and hand hanging loosely over the front edge of the armrest. These questions apply only to your weaker arm.*

Can you bend your wrist back without lifting your forearm? Y N

Can you open your hand? Y N

Can you move your thumb away from the palm of your hand? Y N

*Now move your arm back on the armrest so that the palm of your hand is flat on the armrest and your fingers are hanging loosely over the front edge of the armrest.*

Can you lift at least two fingers while keeping your palm in contact with the armrest? Y N

*Answer the following questions about your weaker arm. It can be placed in any position that makes it easier for you to perform these tasks.*

Can you straighten your elbow? Y N

Can you raise your arm at the shoulder? Y N

Can you pick up a tennis ball and release it? Y N

Can you pick up a washcloth and release it? Y N

**PAIN SCREEN**

Do you have pain that interferes with your life or activities? Y N

If so, which word or words best describe the pattern of your pain?

Continuous

Periodic (sometimes present)

Momentary (lasting a short time)

What kinds of things relieve your pain? \_\_\_\_\_  
\_\_\_\_\_

What kinds of things increase your pain? \_\_\_\_\_  
\_\_\_\_\_

*Please answer each of the following questions using the most appropriate rating on a scale of 0 to 10 where 0=no pain and 10=excruciating pain*

Which rating describes it as its worst during the past week? \_\_\_\_\_

Which rating describes it when it is at its least during the past week? \_\_\_\_\_

Which rating describes your pain on average during the past week? \_\_\_\_\_

## RCT In-Person Participant Screening Form

Date: \_\_\_\_\_ Evaluator \_\_\_\_\_

Participant's name: \_\_\_\_\_

DOB: \_\_\_\_\_

Gender: \_\_\_\_\_

Race: \_\_\_\_\_

Contact person: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Pre-morbid handedness: \_\_\_\_\_

Side of Hemiparesis: \_\_\_\_\_

Date of Stroke: \_\_\_\_\_

Family and Friends (**Required: at least four names and phone numbers of family and friends in case we cannot get hold of the patient**)

Name: \_\_\_\_\_ Relationship: \_\_\_\_\_ Phone: \_\_\_\_\_

ALL BULLETED INCLUSION CRITERIA MUST BE MET

### I. Active Movement

#### 1. Active Wrist and Finger Extension:

*Starting position: Participant's forearm on supporting surface (in pronation) with hand hanging over edge of supporting surface allowing full wrist flexion or subject's available range of motion.*

*Participants must be able to actively extend wrist 10° from the starting position, extend or abduct the thumb at least 10° from the starting position and extend the metacarpophalangeal and interphalangeal joints of at least 2 additional digits 10°. Picks up a washcloth from table and releases it. Must be able to perform each activity at least 3 times in 1 minute. Criteria can be met with a device such as Saebo Glove if participant is willing to use this device consistently during the trial.*

- Extension of wrist: **10° or more**
- Extension or abduction of thumb: **10° or more**
- Extension of MCP and PIP joints at least 2 additional digits: **10° or more**

✓ **Does participant meet these criteria?** Y N

## 2. Active Shoulder Motion

*Participant must be able to actively flex and abduct shoulder to at least 45°. Note: For the purposes of this screening, the flexion may be exhibited from a position ranging from that of strict forward flexion toward scaption (which, on a horizontal plane, is half way between shoulder flexion and abduction); whereas, abduction may be exhibited from a position ranging from scaption to full abduction at the side of the body.*

*Starting position: participant seated in chair with a back; UE resting in subject's lap.*

- Flexion of shoulder: **45° or more**
- Abduction of shoulder: **45° or more**

✓ **Does participant meet these criteria?** Y N

## 3. Active Elbow Extension

*All Groups – Participant must be able to actively extend at least 20° from the 90° position.*

*Starting position: Participant seated in chair with back; UE supported by tester in 90° of shoulder flexion (or maximal shoulder flexion possible if PROM is less than 90°) providing a gravity eliminated position for elbow extension and elbow flexed at 90°.*

- Extension of elbow: **20° or more from 90° flexed position**

✓ **Does the participant meet this criterion?** Y N

## II. Passive ROM:

- Shoulder flexion (90 degrees or more):
- Shoulder Abduction (90 degrees or more):
- Shoulder External Rotation (45 degrees or more):
- Elbow Extension (-30 degrees contracture or less):
- Forearm Supination (45 degrees or more from neutral):
- Forearm Pronation (45 degrees or more from neutral):
- Wrist Extension (to neutral or more):
- MCP Extension (-30 degrees contracture or less):

✓ **Does the participant meet these criteria?** Y N

### **III. Vision/ Hearing:**

*Participants must have adequate vision and hearing to perform testing (with correction).*

- Able to see MAL scales.
- Hear instructions for testing.

✓ **Does the participant meet these criteria?** Y N

### **IV. Communication – Aphasia Criteria**

*Participant must understand what therapist says (e.g., 1-step commands) and be able to indicate a response either verbally or through use of gesture/physical demonstration. Expressive language is not required.*

- Adequate communication ability to participate fully

✓ **Does the participant meet this criterion?** Y N

### **V. Motor Activity Log**

*This criterion is most useful for identifying which participants with higher motor functioning are eligible to participate. There is no maximum level of motor ability for the study, but participants must exhibit non-use of the weaker arm (score less than 2.5 on the QOM portion of the MAL). When non-use is obvious and motor impairment is pronounced, you need not administer MAL.*

- MAL QOM less than 2.5

✓ **Does the participant meet these criteria?** Y N

### **VI. Pain**

*Potential participants will be given the option to self-exclude if they have pain that would be significantly aggravated by participation in the protocol. Consider missed days in carrying out everyday tasks due to pain and excessive discomfort.*

### **VII. Anti-Spasticity Agents:**

*Participants receiving Botox injections may be scheduled after 12 weeks from when the Botox injection was administered. If the participant is using other antispasticity agents such as oral Baclofen, then that information will be noted but will not be used as inclusion / exclusion criteria.*

- More than 12 weeks from last Botox injection at start of trial

Are you currently using Baclofen, Dantrium or any other anti-spasticity agents? Y N

If so, which one? \_\_\_\_\_

If botox, date of last injection? \_\_\_\_\_

✓ Does the participant meet these criteria? Y N

### **VIII. Administer 9-hole peg test**

*If participant qualifies, see whether he/she falls in higher or lower functioning group. Stratification will be based on the participant's ability to complete placement of any number of pegs on the 9-hole peg test within the allotted time (120 seconds).*

**Higher group: can place ANY number of pegs (1-9)**

**Lower group: cannot place any pegs**

✓ Which group is the participant assigned to? \_\_\_\_\_

### **IX: Additional Questions**

*(circle one)*

*Are you able to maintain standing balance for 2 minutes; using UE for support if needed without the assistance of another person?*

Y N

*Are you able to independently and safely transfer to/from the toilet and manage clothing/hygiene?*

Y N

*Are you able to independently stand from a sitting position?*

Y N

*Do you plan to use a device during the trial (e.g., Saebot)?*

Y N

### **X: Summary and Planned Follow-up:**

### **XI: If enrolled...**

Randomization Group? \_\_\_\_\_

Date of Pretest: \_\_\_\_\_

Date of Post-test: \_\_\_\_\_

Date of 6-month follow-up: \_\_\_\_\_

## Treatment materials – CI therapy

### Checklist

Note: Bolded items are separate sheets within the treatment packet to be completed

### Prior to Treatment (after pre-test)

1. Provide the activity monitors to participants and demonstrate use.
2. Instruct them to wear the activity monitors on both arms for 2 days before treatment to establish a baseline of arm use.
3. Make sure participant knows to charge them overnight every night.
4. Instruct participant to watch CIMT videos on YouTube. Give them the link.

### Treatment Day –1 (TD 1)

1. Turn video camera on & show participant ID, treatment day, date, and group
2. Complete **Treatment Received Form**
3. Introduce the **Treatment Contract** by reading/explaining each component of the therapy. Briefly present the research.
  - discuss the need for massed practice with the weaker arm and limited use of the stronger arm to drive brain plasticity.
  - discuss how quality of life improvements relate directly to the amount of use for daily activities, regardless of motor ability.
4. **Home Achievement Record** portion of Treatment Contract.
  - Compile list of daily activities done on both weekdays and weekends (one list)
  - Photocopy daily activities list prior to categorizing level of involvement of the weaker arm in each task (10 copies). Provide 1 copy to client to complete prior to next session.
  - Discuss involvement of the weaker arm in each task with problem-solving.
5. **Caregiver contract**. Provide instruction to family member/caregiver on problem-solving approach. (“You’ll notice that I used a particular approach to help clients come up with solutions to some of the barriers to using the weaker arm.”)
  - “Say” – They come up with a plan. No questioning.
  - “Do” – They try it out
  - “Check” - To note what worked and what didn’t. Revise the plan.
6. Ask participant if he/she watched the CIMT videos on YouTube. If they have not yet, assign as homework.
7. Ask participant about adverse events during previous session(s) and fill out **Adverse Event Reporting Form** if need be
8. Donn the mitt

9. Perform ~9 shaping tasks—document on **Task List, Shaping Data Sheets,** and **Shaping Graphs** (1 per task)
10. Administer the full MAL—all 28 items using the How Well Scale only (add to **MAL spreadsheet**)
11. Turn video camera off and add comments to **Therapist Treatment Recording Log**
12. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Treatment Day- 2 (TD 2)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check the mitt time and record it on the Task List; don the mitt. If mitt wear time is low, problem-solve compliance as needed.
3. Administer a half MAL using the How Well Scale only (record responses on **MAL spreadsheet**)
4. Review the Home Achievement Record with the patient
5. Perform ~9 additional shaping tasks (different from those on TD 1)—document on **Task List, Shaping Data Sheets,** and **Shaping Graphs** (1 per task)
6. Explain the **Home Skill Assignment List (HSA)** and select the 10 items
7. Give the patient the next **Home Achievement Record** form
8. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
9. Turn video camera off and add comments to **Therapist Treatment Recording Log**
10. Store the video on the encrypted hard drive under the correct group and session subfolder
11. Ask participant if he/she watched the CIMT videos on YouTube. If they have not yet, assign as homework.

### **Treatment Day- 3 (TD 3-5, 7-10)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check the mitt time and record it on the Task List; don the mitt. If mitt wear time is low, problem-solve compliance as needed.
3. Administer a half MAL using the How Well Scale only (record responses on **MAL spreadsheet**)
4. Review the HSA
5. Review the Home Achievement Record with the patient
6. Repeat the 9 shaping tasks from TD1/TD2 (alternating between treatment days); can now consider shaping the tasks—document on **Task List, Shaping Data Sheets** and **Shaping Graphs**
7. Select the 10 items for the **Home Skill Assignment (HSA)** list
8. Give the patient the next **Home Achievement Record** form

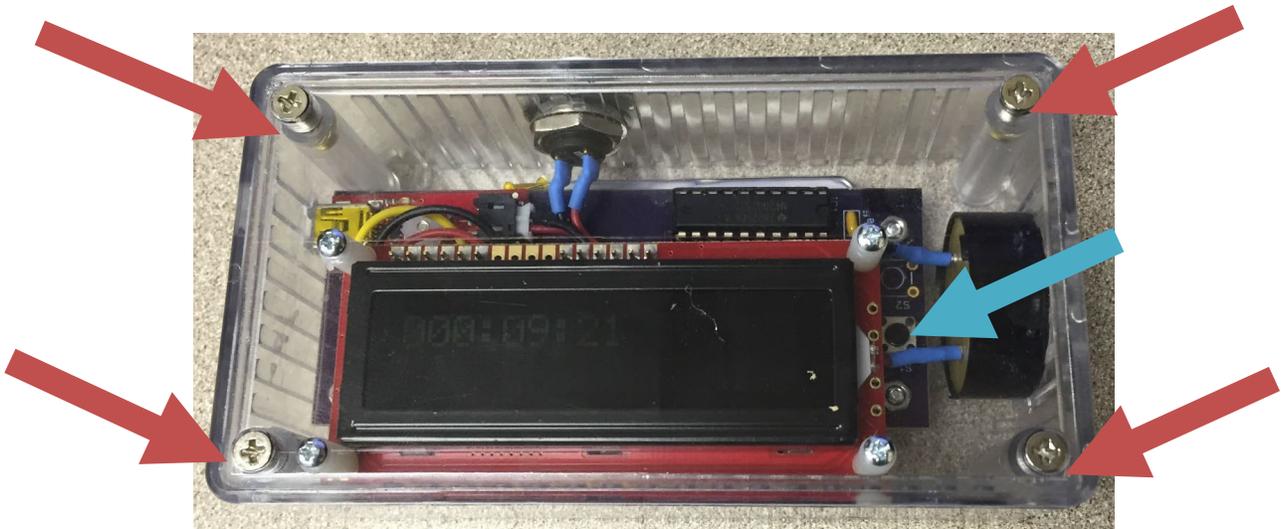
9. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
10. Ask participant if he/she watched the CIMT videos on YouTube. If they have not yet, assign as homework.
11. Turn video camera off and add comments to **Therapist Treatment Recording Log**
12. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Treatment Day- 6 (TD 6)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check the mitt and record it on the Task List; donn the mitt. If mitt wear time is low, problem-solve compliance as needed.
3. Administer a full MAL – all 28 items using the How Well Scale only (record responses on **MAL spreadsheet**)
4. Review the HSA
5. Review the weekend Home Achievement Record with the patient
6. Repeat the 9 shaping tasks from TD2; can now consider shaping the tasks— document on **Task List, Shaping Data Sheets** and **Shaping Graphs**
7. Select the 10 items for the **Home Skill Assignment (HSA)** list
8. Give the patient the next **Home Achievement Record** form
9. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
10. Ask participant if he/she watched the CIMT videos on YouTube. If they have not yet, assign as homework.
11. Turn video camera off and add comments to **Therapist Treatment Recording Log**
12. Store the video on the encrypted hard drive under the correct group and session subfolder

### **How to reset mitt device**

1. Unscrew 4 outer edge corners (Red Arrows)
2. Hold down black button for ~5 seconds (Blue Arrow)
3. Re-screw 4 outer edge corners



### **MAL in follow-up**

MAL How Well administered with problem solving weekly for 1<sup>st</sup> month via phone.  
20 min. each. (4 times total)

- Record responses on **MAL spreadsheet**

## **Description of Therapy**

Constraint Induced Movement Therapy or CI therapy is thought to work because it has been shown to produce a large "rewiring" of the brain; that is, after treatment, a larger part of the brain is involved in producing movement of the weaker arm than before therapy. It also has the effect of overcoming a strong tendency not to use the weaker arm ("learned nonuse") that develops in the early post-stroke period.

Research has shown that patients can "learn" to improve the motor ability of the weaker parts of their bodies and thus cease to rely exclusively or primarily on the stronger parts. For this learning and rewiring to occur, two things have to happen:

1. Intensive training of the weaker arm in the clinic. This will occur through intensive training of the weaker arm and hand in the laboratory for 3 hours a day for 10 days.
2. Use of the weaker arm for daily activities (more than the stronger arm) OUTSIDE the clinic. This is linked to structural changes in the brain and improved quality of life. Research has shown that these improvements are absent when improved motor function does not carry over to daily life. Three things will help you carry-over in-lab improvements to your daily activities.
  - a. Restraint of the stronger arm in a **padded mitt** for a large number of waking hours over the treatment period in the laboratory and at home.
  - b. The procedures involved in use of the mitt will be outlined in a **Treatment Contract** established by you and the therapist at the beginning of treatment. This contract is used to identify specific daily tasks that your weaker arm will perform and times when the mitt will be worn. Safety is always the first consideration when determining the appropriate times for use of the weaker arm and the use of the mitt on the stronger arm. For example, if you require the use of a quad cane for safe walking, then the mitt would be removed when walking to ensure maximal safety when the quad cane is used. As part of this contract, you will be asked to complete a **Home Achievement Record** that focuses on the use of the weaker arm in your home and on the use of the mitt outside the laboratory.
  - c. A **home practice program** (30 minutes daily) will be devised for you to carry out with your weaker arm when you are out of the clinic.

## **Obtaining the Best Results**

You must be willing to work diligently during your treatment program. If portions of the therapy are dropped, the treatment has been found to be much less effective. Also, it would be harder for us to show definitive results from this study when people deviate from the study protocol (similar to studying the relative effectiveness of different medicines when they are not taken as prescribed). If you are having difficulty keeping up with the protocol, please let your project therapist know. A solution can be worked out to help you achieve the most from the therapy and minimize deviations from the prescribed therapy.

**Treatment Contract**

I agree to the following treatment expectations:

- I will attempt to use only my weaker arm for nearly all activities outside the clinic (listed in the Home Achievement Record form), including social situations. I will attempt to use my weaker arm alone in all these activities, even if I had previously been using only my stronger arm for some of those tasks.
- The only times that I will involve my stronger arm in my daily activities are if my safety could in any way be affected or for two-handed tasks.
  - Activities for which I can remove my mitt:  
\_\_\_\_\_
- I will wear the mitt on my stronger arm for a target 10 hours/day to break the habit of relying too much on my stronger arm for daily activities.
- I will not remove the mitt at any time or for any task for which I have agreed to wear it, EXCEPT under 3 conditions: 1) if it could negatively affect my safety, 2) for two-handed tasks, and 3) for tasks involving water.
- If I need to reschedule a therapy session, I will call as soon as possible and no later than 24 hours in advance. I will plan to arrive on time to all therapy sessions.
- I will practice 10 activities of importance to me with my weaker hand for a total of 30 minutes per treatment day (Home Skill Assignment).

Goals for Treatment (what you're working towards):

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Signature of Therapist

## Caregiver Contract

I agree to assist with providing CI therapy in the following ways:

- I will allow my family member to take ownership and responsibility for the treatment.
- I will assist with a task by serving as a "second arm" to enable my family member to avoid using the stronger arm during the treatment period for certain tasks discussed in the Home Achievement Record.
- I will relinquish my "caregiver hat" and will not perform any activities that my family member has agreed to accomplish with the weaker hand, even when my family member appears to be struggling.
- I will only assist with upper extremity tasks if safety is a concern or if my assistance will provide additional opportunities for my family member to use the weaker arm (e.g., serving as a "second arm"). When assistance with a task is required I will allow my family member to solve the problem using the "Say," "do," "check" approach:
  - Say: What else could you try?
  - Do: Let your family member try the solution, even if you don't think it will work.
  - Check: What worked? How can the plan be revised for better success?
- I may provide reminders for my family member to engage in therapy tasks if he or she has indicated that they would be helpful (e.g., reminders to do Home Skill Assignments).
- I understand that the treatment will be extremely challenging and I will be supportive and encouraging.
- I will praise my family member's effort at using the weaker hand, especially during tasks that are difficult.
- I will be open to simple adaptations in the home if they enable my family member to use their weaker arm more frequently (such as using plastic dishware temporarily).
- I understand that using the weaker arm may result in more spills and that this is a necessary step toward improving function of the weaker arm. I will be supportive when this happens.
- I agree to attend therapy sessions when possible.

---

Signature of Therapist

---

Signature of Caregiver



DESCRIBE ACTIVITY		I USED ..... ( <input checked="" type="checkbox"/> check all that apply)			
Mitt ON <input checked="" type="checkbox"/>		Affected Arm	Both Arms	Help Needed	Comments
DESCRIBE ACTIVITY		I USED ..... ( <input checked="" type="checkbox"/> check all that apply)			



## Potential Home Practice Tasks

### 1. Bathroom Tasks

### Problem Solving Suggestions

#### **A. Bathing**

- Apply soap while bathing
- Use a towel (after bathing)
- Remove/replace towel on towel rack
- Other \_\_\_\_\_

#### **B. Toileting**

- Flush the commode
- Lift the toilet lid/ close the toilet lid
- Unroll toilet paper & tear off
- Remove/ replace toilet paper roll
- Other \_\_\_\_\_

#### **C. Grooming**

- Apply lotion to body (other than face)
- Pump a soap dispenser
- Use tissue or handkerchief for wiping nose/  
blowing nose
- Remove cap of toothpaste
- Apply toothpaste to brush
- Brush dentures
- Sort weekly medications
- Other \_\_\_\_\_

#### **D. Bathroom Access**

- Clean bathroom sink
- Open a sliding glass door or sliding  
shower/closet door
- Open /close cabinet

- Open/ close shower curtain
- Open/ close window
- Open/ close medicine cabinet
- Other \_\_\_\_\_

## **2. Bedroom Tasks**

## **Problem Solving Suggestions**

### **A. Dressing**

- Put on pants or undergarments
- Put on a pullover shirt
- Use a zipper pull
- Feed belt through belt loops
- Buckle a belt
- Put on / take off watch band
- Put on glasses
- Other \_\_\_\_\_

### **B. Bedroom Access**

- Take down and put up clothes on hangers (or just hangers alone)
- Organize shoes in closet
- Organize socks in drawer
- Make-up bed
- Put dirty clothes in hamper
- Steady yourself while standing
- Open a sliding glass door or sliding shower/ closet door
- Open /close cabinet
- Dust furniture in bedroom
- Open/ close window
- Other \_\_\_\_\_

**C. Bed Mobility**

- Roll over in bed
- Sit up on the side of the bed
- Push off/ pull up bed covers
- Other \_\_\_\_\_

**3. Kitchen Tasks**

**Problem Solving Suggestions**

**A. Dish Washing**

- Wash dishes in sink
- Squeeze liquid soap onto dishes, dish rag, or sponge
- Place dishes in drying rack or dishwasher
- Sort utensils and put away
- Put up dishes/ pans into cabinets/ drawers
- Operate buttons and dials on dishwasher
- Other \_\_\_\_\_

**B. Meal Preparation**

- Cut vegetables or fruits with a knife (not peeling)
- Spread butter, jelly, peanut butter, mayonnaise, etc on bread
- Stir or mix ingredients for recipe (not on stove)
- Pour the milk or juice or liquid into cup or bowl
- Serve plate by scooping food from on dish or pan to plate
- Other \_\_\_\_\_

**C. Kitchen Access**

- Open /close microwave door
- Scoop coffee into coffee maker
- Get milk or juice out of the refrigerator

- Retrieve food item from pantry
- Clean kitchen sink
- Open /close cabinet
- Other \_\_\_\_\_

#### **4. Utility Room**

#### **Problem Solving Suggestions**

##### **A. Clothes Washing/ Drying**

- Sort dirty clothes for washing
- Put clothes in washer machine
- Turn dials and push buttons to start washer machine/dryer
- Twist off the liquid detergent cap
- Pour washing detergent into washer machine
- Open and close washer machine door and dryer door
  
- Switch clothes from washer machine to the dryer
- Other \_\_\_\_\_

##### **B. Utility Room Access**

- Open a sliding glass door or sliding shower/ closet door
- Open /close cabinet
- Other \_\_\_\_\_

#### **4. Pet Care Tasks**

##### **C. Feeding Pet**

- Feed pet by scooping out food into bowl
- Open can of pet food and serve into pet bowl
- Give pet water
- Give pet a treat
- Other \_\_\_\_\_

**D. Pet Care**

- Brush or groom pet
- Pat or stroke your pet from head to tail
- Scratch behind pet's ears
- Open and close door for pet
- Other \_\_\_\_\_

**5. Office Tasks**

**Problem Solving Suggestions**

---

**A. Computer Tasks**

- Type on computer keyboard
- Use mouse on computer
- Other \_\_\_\_\_

**B. Mail Tasks**

- Place stamps on mail
- Open mail
- Other \_\_\_\_\_

**C. Filing Tasks**

- Open file cabinet
- Place files in file cabinet
- Other \_\_\_\_\_

**D. Misc.**

- Dial telephone
- Press buttons of a keypad
- Use calculator
- Use scissors
- Other \_\_\_\_\_

## **6. Dining Tasks (home or restaurant including fast food)**

### **A. Set-up for Meal**

- Set the table
- Pop-top of beverage can
- Twist top off bottled drink
- Use salt and pepper
- Place straw in plastic lid of cup
- Unfold and place napkin in lap
- Open food containers and removing wrapping
- Apply condiments from bottle (like ketchup, mustard, salad dressing.)
- Other \_\_\_\_\_

### **B. Other Meal/ Restaurant Related Activities**

- Wipe mouth with napkin
- Hold menu
- Push or pull restaurant door
- Other \_\_\_\_\_

### **C. Money Management**

- Remove bills from a wallet or purse
- Take individual coins out of a pocket or purse
- Hand cashier money or swipe credit card
- Other \_\_\_\_\_

## **7. Outside Tasks (like yard work, etc)**

### **A. Gardening**

- Use clippers or shears to do light trimming of shrubs or other outside plants
- Weed a flowerbed or potted plant
- Pick vegetable garden (like tomatoes, peas, beans)
- Turn on/off hose at the faucet

## **Problem Solving Suggestions**

## **Problem Solving Suggestions**

- Remove and replace hose on faucet
- Other \_\_\_\_\_

**B. Mailbox**

- Open mailbox
- Remove mail from mailbox
- Place outgoing mail in mailbox
- Lift up mailbox flag
- Other \_\_\_\_\_

**7. Workshop Tasks**

**C. Tasks** \_\_\_\_\_

- Organize toolbox
- Other \_\_\_\_\_

**Other Home Tasks**

**D. Tasks**

- Turn on/ off radio
- Tune radio
- Hold newspaper for reading
- Adjust air conditioner or heater
- Water inside plants
- Other \_\_\_\_\_

**8. Grocery Store Tasks**

**A. Tasks** \_\_\_\_\_

- Make a grocery list
- Select assorted sized fruits/ vegetables and place in basket
- Select items from grocery shelves and place in basket

**Problem Solving Suggestions**

- Open freezer doors
- Push grocery basket
- Unload groceries for purchase
- Remove bills from a wallet
- Take individual coins out of a pocket or purse
- Hand cashier money or swipe credit card
- Other \_\_\_\_\_

### **Community Tasks (other)**

#### **B. Tasks**

- Push elevator buttons
- Use ATM machine
- Other \_\_\_\_\_

#### **C. Beverage Machine Use**

- Feed a dollar into beverage machine
- Feed coins into beverage machine/ retrieve any change that is returned
- Select desired beverage by pressing buttons on beverage machine
- Retrieve chosen beverage
- Other \_\_\_\_\_

### **9. Car Tasks**

### **Problem Solving Suggestions**

#### **A. Car Buttons, Levers, Handles, Access, etc**

(NOTE: do as a passenger in the car)

- Adjust car radio/ tape player/ CD player
- Operate window buttons
- Adjust car seat
- Adjust side mirror
- Access glove box
- Place & remove items from the glove box
- Other \_\_\_\_\_

**B. Seat Belt Use**

- Put on seat belt
- Release seat belt
- Other \_\_\_\_\_

**C. Car Access**

- Open / close car door
- Other \_\_\_\_\_

**D. Car Care**

- Wash car
- Wax car
- Wash windows of car
- Check oil (with cool engine)
- Other \_\_\_\_\_

**9. Hobby Tasks (example: knitting, painting, golfing, fishing, crossword puzzles, play cards)**

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**Other Tasks (other tasks that have not been included on this list)**

- F.** \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**Home Practice Recording Log**

Subject ID: \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_ Day M T W Th F Sat Sun

You should practice Home Skills Assignments for at least 30 minutes per day.

<b>NO.</b>	Activities or components of activities to be tried (i.e., washing hands includes rinsing hands, getting soap, drying hands, etc.).....	Attempted Y/N	Number Times/Day	Comments

**Motor Activity Log Treatment Record**

<b>MAL Spreadsheet (How Well Scale Only)</b>	TD1	TD2	TD3	TD4	TD5	TD6	TD7	TD8	TD9	TD10	F/U 1	F/U 2	F/U 3	F/U 4
1. Turn on a light switch														
2. Open drawer														
3. Remove an item of clothing from a drawer														
4. Pick up phone														
5. Wipe off a kitchen counter or other surface														
6. Get out of car														
7. Open refrigerator														
8. Open a door by turning a door knob/handle														
9. Use a TV remote control														
10. Wash your hands (lathering and rinsing hands)														
11. Turning water on/off with knob/lever on faucet														
12. Dry your hands														
13. Put on your socks														
14. Take off your socks														
15. Put on your shoes														
16. Take off your shoes														
17. Get up from a chair with armrests														
18. Pull chair away from table before sitting down														
19. Pull chair toward table after sitting down														
20. Pick up a glass, bottle, drinking cup, or can														
21. Brush your teeth														
22. Use a key to unlock a door														
23. Carry an object in your hand														
24. Use a fork or spoon for eating														
25. Comb your hair														
26. Pick up a cup by a handle														
27. Button a shirt														
28. Eat half a sandwich or finger foods														
MEAN SCORE														

**Motor Practice Recording Forms**

**Feedback Graph**

**SID:** \_\_\_\_\_

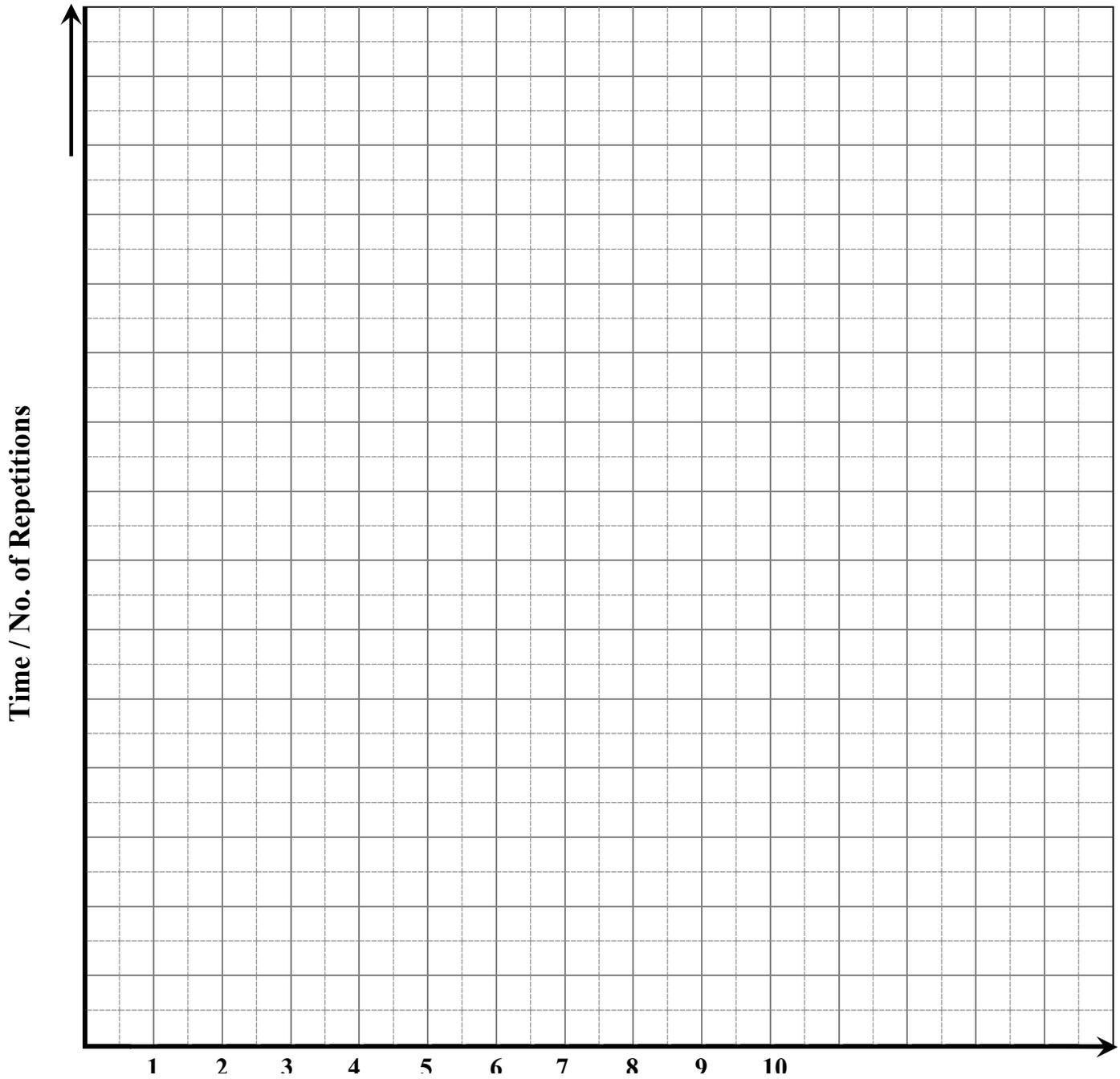
**Date:** \_\_\_\_\_

**Name:** \_\_\_\_\_

**Day:** \_\_\_\_\_

**Trainer:** \_\_\_\_\_

**Task:** \_\_\_\_\_





## Shaping Data Sheet

Task: \_\_\_\_\_ Pt Initials: \_\_\_\_\_ Subject ID: \_\_\_\_\_

Date: \_\_\_\_\_ Trmt Day #: \_\_\_\_\_ Time: \_\_\_\_\_ Therapist: \_\_\_\_\_

**Shaping Task Description:** *Location specifies: Is the task setup the same way?*

Place the \_\_\_\_\_: (check one)

- Center of the patient
- To the right / left (circle one) of the patient
- Other \_\_\_\_\_
- \_\_\_\_\_ inches from the Edge of Table
- \_\_\_\_\_ inches from midline
- \_\_\_\_\_ other \_\_\_\_\_

Height: \_\_\_\_\_ inches \_\_\_\_\_

Place the \_\_\_\_\_: (check one)

- Center of the patient
- To the right / left (circle one) of the patient
- Other \_\_\_\_\_
- \_\_\_\_\_ inches from the Edge of Table
- \_\_\_\_\_ inches from midline
- \_\_\_\_\_ other \_\_\_\_\_

Height: \_\_\_\_\_ inches \_\_\_\_\_

**Summary of Task:** (What is the patient doing? What movements are emphasized? Any assistance from Therapist?, etc.)

\_\_\_\_\_  
 \_\_\_\_\_

Parameter Measured (ParaM): \_\_\_\_\_

*Ways to Shape/Make the task more challenging:*

Parameter 1 Varied (ParaV1): \_\_\_\_\_

Parameter 2 Varied (ParaV2): \_\_\_\_\_

Parameter 3 Varied (ParaV3): \_\_\_\_\_

Trial	ParaM	ParaV1	ParaV2	ParaV3	Comments
					-Note drop, recovery, or repositioning -Note techniques that work or don't work
1					
2					
3					
4					
5					Avg (X) =
6					
7					
8					
9					
10					Avg (X) =

**Video Recording Log**

Treatment Day:	Comments about recording (i.e. session completely recorded, battery died, etc.)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

## Treatment materials – Gaming CI therapy Groups

### Checklist Self-Gaming

Note: Bolded items are separate sheets within the treatment packet to be completed

### Prior to Treatment (after pre-test)

1. Provide the activity monitors to participants and demonstrate use.
2. Instruct them to wear the activity monitors on both arms for 2 days before treatment to establish a baseline of arm use.
3. Make sure participant knows to charge them overnight every night.
4. Provide the smart watch to participants and demonstrate use (give them the **instructions** to take home with them).
5. Instruct them to wear the watch on the less affected arm for 2 days before treatment to establish a baseline of “normal” arm movement counts.
6. Have them record the values on the watch right before going to bed on the **Limb Activation Log**.
7. Instruct participant to watch CIMT videos on YouTube. Give him/her the link.

### In-clinic Treatment Day 1 (2 hours)

1. Turn video camera on & say participant ID, treatment day, and group
2. Only record the required activities for review for each session, turning the camera off after each activity
3. Complete **Treatment Received Form**
4. Review 4 components of intervention: intensive practice through game, computerized MAL, smart watch, Transfer Package of carry-over techniques. Emphasize that the game is only part of the therapy and that the other components are at least as important. The other components drive the brain plasticity. (~10 min)
5. Instruction in game play and customization of game to individual. (~30 minutes)
  - Occurs in home on participants’ own schedule.
  - 1.5 hours per day on 10 treatment days. Participants are encouraged to break this down into at least 3 separate play sessions per day (15-30 min sessions are optimal).
  - Tell the participant to record their amount of game play each day on the **Game Log**
  - Write down the randomly generated Game ID on one of the site business cards and instruct the participant to keep this with them and bring it to every visit (this is how you will access their game data)
  - Instruction on hot spot set-up
6. Instruction in use of smart watch (~5 min). Have client record the daily count on the **Limb Activation Log** each night before going to bed
7. Introduce the **Treatment Contract** by reading/explaining each component of the therapy. Briefly present the research. (15 min)
  - discuss the need for massed practice with the weaker arm and limited use of the stronger arm to drive brain plasticity.
  - discuss how quality of life improvements relate directly to the amount of use for daily activities, regardless of motor ability.

8. **Home Achievement Record** portion of Treatment Contract. (45 min)
  - Compile list of daily activities done on both weekdays and weekends (one list)
  - Photocopy daily activities list prior to categorizing level of involvement of the weaker arm in each task (10 copies). Provide 1 copy to client to complete prior to next session.
  - Discuss involvement of the weaker arm in each task with problem-solving.
9. Explain the **Home Skill Assignment List (HSA)** and select 10 items (15 min)
10. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
11. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
12. Add comments to **Therapist Treatment Recording Log**
13. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Game Play**

1. TOTAL PLAY TIME SHOULD BE 15 HOURS OVER 3 WEEKS.
2. Occurs in home on participants' own schedule. 1.5 hours per day on 10 treatment days. Participants are encouraged to break this down into at least 3 separate play sessions per day (15-30 min sessions are optimal).
3. Missed game play should be made up during off days.

### **In-clinic Treatment Days ~Days 2, 3, 4 (1 hour)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check game play compliance
  - a. Click on Report Generator App (cannot be opened behind firewall)
  - b. A black box pops up that says "Input User ID"
  - c. Enter the participant's Game ID under the "Input User ID" prompt (this ID is found on the participant's business card)
  - d. Hit Enter
  - e. Report is generated (it works best if the computer you're working from has Excel)
3. Check compliance with smart watch. Review daily movement counts/problem-solve if low use.
4. Review in-game MAL with problem-solving.
5. Review **Home Achievement Record** with problem-solving.
6. **Home Skill Assignment**, 10 items (may be same or different than 1<sup>st</sup> HSA).
7. Remind participant about computerized MAL for next 4 weeks.
8. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
9. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
10. Turn video camera off and add comments to **Therapist Treatment Recording Log**
11. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Follow-up**

1. MAL administered through REDCap survey or mail if no internet access weekly for 4 weeks.

## Checklist Tele-Gaming

Note: Bolded items are separate sheets within the treatment packet to be completed

### Prior to Treatment (after pre-test)

1. Provide the activity monitors to participants and demonstrate use.
2. Instruct them to wear the activity monitors on both arms for 2 days before treatment to establish a baseline of arm use.
3. Make sure participant knows to charge them overnight every night.
4. Provide the smart watch to participants and demonstrate use (give them the **instructions** to take home with them).
5. Instruct them to wear the watch on the less affected arm for 2 days before treatment to establish a baseline of “normal” arm movement counts.
6. Have them record the values on the watch right before going to bed on the **Limb Activation Log**.
7. Instruct participant to watch CIMT videos on YouTube. Give him/her the link.

### In-clinic Treatment Day 1 (2 hours)

1. Turn video camera on & say participant ID, treatment day, and group
2. Complete **Treatment Received Form**
3. Review 4 components of intervention: intensive practice through game, computerized MAL, smart watch, Transfer Package of carry-over techniques. Emphasize that the game is only part of the therapy and that the other components are at least as important. The other components drive the brain plasticity. (~10 min)
4. Instruction in game play and customization of game to individual. (~30 minutes)
  - Occurs in home on participants’ own schedule.
  - 1.5 hours per day on 10 treatment days. Participants are encouraged to break this down into at least 3 separate play sessions per day (15-30 min sessions are optimal).
  - Tell the participant to record their amount of game play each day on the **Game Log**
  - Write down the randomly generated Game ID on one of the site business cards and instruct the participant to keep this with them and bring it to every visit (this is how you will access their game data)
  - Instruction on hot spot set-up
5. Instruction in Bluejeans teleconferencing & give participant the **Bluejeans Tip Sheet**
6. Instruction in Hotspot Setup
7. Instruction in use of smart watch (~5 min). Have client record the daily count on the **Limb Activation Log** each night before going to bed.
8. Introduce the **Treatment Contract** by reading/explaining each component of the therapy. Briefly present the research. (15 min)
  - discuss the need for massed practice with the weaker arm and limited use of the stronger arm to drive brain plasticity.
  - discuss how quality of life improvements relate directly to the amount of use for daily activities, regardless of motor ability.
9. **Home Achievement Record** portion of Treatment Contract. (45 min)
  - Compile list of daily activities done on both weekdays and weekends (one list)

- Photocopy daily activities list prior to categorizing level of involvement of the weaker arm in each task (10 copies). Provide 1 copy to client to complete prior to next session.
  - Discuss involvement of the weaker arm in each task with problem-solving.
10. Explain the **Home Skill Assignment List (HSA)** and select 10 items (15 min)
  11. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
  12. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
  13. Turn video camera off and add comments to **Therapist Treatment Recording Log**
  14. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Game Play**

1. TOTAL PLAY TIME SHOULD BE 15 HOURS OVER 3 WEEKS.
2. Occurs in home on participants' own schedule. 1.5 hours per day on 10 treatment days. Participants are encouraged to break this down into at least 3 separate play sessions per day (15-30 min sessions are optimal).
3. Missed game play should be made up during off days.

### **Video consultation Day 2 (1 hour)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check game play compliance
  - a. Click on Report Generator App (cannot be opened behind firewall)
  - b. A black box pops up that says "Input User ID"
  - c. Enter the participant's Game ID under the "Input User ID" prompt (this ID is found on the participant's business card)
  - d. Hit Enter
  - e. Report is generated (it works best if the computer you're working from has Excel)
3. Check compliance with smart watch. Review daily movement counts/problem-solve if low use.
4. Review in-game MAL with problem-solving.
5. Review **Home Achievement Record** with problem-solving.
6. **Home Skill Assignment**, 10 items (may be same or different than 1<sup>st</sup> HSA).
7. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
8. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
9. Turn video camera off and add comments to **Therapist Treatment Recording Log**
10. Store the video on the encrypted hard drive under the correct group and session subfolder

### **In-clinic Treatment Days ~Days 3, 5, 8 (1 hour)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Check game play compliance
  - a. Click on Report Generator App (cannot be opened behind firewall)
  - b. A black box pops up that says "Input User ID"
  - c. Enter the participant's Game ID under the "Input User ID" prompt (this ID is found on the participant's business card)

- d. Hit Enter
- e. Report is generated (it works best if the computer you're working from has Excel)
3. Check compliance with smart watch. Review daily movement counts/problem-solve if low use.
4. Review in-game MAL with problem-solving.
5. Review **Home Achievement Record** with problem-solving.
6. **Home Skill Assignment**, 10 items (may be same or different than 1<sup>st</sup> HSA).
7. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be.
8. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
9. Turn video camera off and add comments to **Therapist Treatment Recording Log**
10. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Video consultation Days 4, 6, 7, 9, 10 (20 min)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Review in-game MAL with problem-solving. (10 min)
  - a. Click on Report Generator App (cannot be opened behind firewall)
  - b. A black box pops up that says "Input User ID"
  - c. Enter the participant's Game ID under the "Input User ID" prompt (this ID is found on the participant's business card)
  - d. Hit Enter
  - e. Report is generated (it works best if the computer you're working from has Excel)
3. Review **Home Achievement Record** with problem-solving (5 min)
4. **Home Skill Assignment**, 10 items (may be same or different than 1<sup>st</sup> HSA). (5 min)
5. Remind participant about computerized MAL for next 4 weeks.
6. Ask participant if he/she watched the CIMT videos on YouTube. If he/she has not, assign as homework.
7. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be
8. Turn video camera off and add comments to **Therapist Treatment Recording Log**
9. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Follow-up**

1. MAL administered via phone call weekly for 4 weeks. Therapist is to complete the **MAL in follow-up document** each time.

## Description of Therapy

### What is CI Therapy?

Constraint Induced Movement Therapy or CI therapy is thought to work because it has been shown to produce a large "rewiring" of the brain; that is, after treatment, a larger part of the brain is involved in producing movement of the weaker arm than before therapy. It also has the effect of overcoming a strong tendency not to use the weaker arm ("learned nonuse") that develops in the early post-stroke period.

Research has shown that patients can "learn" to improve the motor ability of the weaker parts of their bodies and thus cease to rely exclusively or primarily on the stronger parts. For this learning and rewiring to occur, two things have to happen:

1. Intensive training of the weaker arm. This will occur through playing the Recovery Rapids video game in your home for 1.5 hours per day for 10 days.
2. Use of the weaker arm for daily activities (more than the stronger arm) OUTSIDE the clinic. This is linked to structural changes in the brain and improved quality of life. Research has shown that these improvements are absent when improved motor function does not carry over to daily life. Three things will help you carry-over in-lab improvements to your daily activities (i.e., change your habit of always using the stronger arm).
  - a. A smart watch that will record your activity with the weaker arm. The goal will be to dramatically increase the number of arm movements made with your weaker arm over the course of the intervention.
  - b. A **Treatment Contract** that will identify specific daily tasks that your weaker arm will perform each day. Safety is always the first consideration when determining the appropriate times for use of the weaker arm (e.g., you may not want to use a cane in the weaker hand). As part of this contract, you will be asked to complete a **Home Achievement Record** each day to check your progress with building new habits of using the weaker arm in your home.
  - c. A **home practice program** (30 minutes daily) will be devised for you to carry out with your weaker arm when you are out of the clinic.

### Obtaining the Best Results

You must be willing to work diligently during your treatment program. If portions of the therapy are dropped, the treatment has been found to be much less effective. Also, it would be harder for us to show definitive results from this study when people deviate from the study protocol (similar to studying the relative effectiveness of different medicines when they are not taken as prescribed). If you are having difficulty keeping up with the protocol, please let your project therapist know. A solution can be worked out to help you achieve the most from the therapy while minimizing deviations from the prescribed program.

**Treatment Contract**

I agree to the following treatment expectations:

- I will use only my weaker arm for nearly all activities outside the clinic (listed in the Home Achievement Record form), including social situations. I will attempt to use my weaker arm alone in all these activities, even if I had previously been using only my stronger arm for some of those tasks.
- The only times that I will involve my stronger arm in my daily activities are if my safety could in any way be affected or for two-handed tasks.

Activities for which I should use my stronger arm:

\_\_\_\_\_

- I will wear the smart watch on my weaker arm for a target 10 hours/day to break the habit of relying too much on my stronger arm for daily activities. I will record the number of movements made by my weaker arm each night with the goal of exceeding the number of movements typically made with my stronger arm.
- If I need to reschedule a therapy session, I will call as soon as possible and no later than 24 hours in advance. I will plan to arrive on time to all therapy sessions.
- I will practice 10 activities of importance to me with my weaker hand for a total of 30 minutes per treatment day (Home Skill Assignment).

Goals for Treatment (what I'm working towards):

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

\_\_\_\_\_

Signature of Patient

\_\_\_\_\_

Signature of Therapist

## Caregiver Contract

I agree to assist with providing CI therapy in the following ways:

- I will allow my family member to take ownership and responsibility for the treatment.
- I will assist with a task by serving as a "second arm" to enable my family member to avoid using the stronger arm during the treatment period for certain tasks discussed in the Home Achievement Record.
- I will relinquish my "caregiver hat" and will not perform any activities that my family member has agreed to accomplish with the weaker hand, even when my family member appears to be struggling.
- I will only assist with upper extremity tasks if safety is a concern or if my assistance will provide additional opportunities for my family member to use the weaker arm (e.g., serving as a "second arm"). When assistance with a task is required I will allow my family member to solve the problem using the "Say," "do," "check" approach:
  - Say: What else could you try?
  - Do: Let your family member try the solution, even if you don't think it will work.
  - Check: What worked? How can the plan be revised for better success?
- I may provide reminders for my family member to engage in therapy tasks if he or she has indicated that they would be helpful (e.g., reminders to do Home Skill Assignments).
- I understand that the treatment will be extremely challenging and I will be supportive and encouraging.
- I will praise my family member's effort at using the weaker hand, especially during tasks that are difficult.
- I will be open to simple adaptations in the home if they enable my family member to use their weaker arm more frequently (such as using plastic dishware temporarily).
- I understand that using the weaker arm may result in more spills and that this is a necessary step toward improving function of the weaker arm. I will be supportive when this happens.
- I agree to attend therapy sessions when possible.

---

Signature of Therapist

---

Signature of Caregiver

**Home Achievement Record of Treatment Contract**

**Subject ID:** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ **Day** (circle) M T W Th F Sat Sun

**Therapist:** \_\_\_\_\_

DESCRIBE ACTIVITY	I USED ..... ( <input checked="" type="checkbox"/> check all that apply)			Comments
	Affected Arm	Both Arms	Help Needed	
Push self up out of bed				





**In-clinic Treatment Schedule**

453 W 10<sup>th</sup> Ave. Columbus, OH 43210

To help us obtain the most meaningful study results, we would greatly appreciate your efforts to reschedule missed appointments or game play time. This will ensure that all study groups get the same amount of total motor practice. Your participation will help us learn whether an in-home therapy can lead to gains in motor functioning that are as large as with more costly in-clinic therapies. We really appreciate your contribution to science!

Event	Date	Time In	Time Out	Location
Pretest (2 hours)				
In Clinic Day 1 (2 hours)				
In Clinic Day 2 (1 hour)				
In Clinic Day 3 (1 hour)				
In Clinic Day 4 (1 hour)				
Post Test (2 hours)				
6 Month Follow Up				





**Game Gestures Key**

Gesture	Starting Position	Ending Position
Rowing		
Move toward affected side		
Move toward unaffected side		
Bottles		
Fishing		

Parachutes				
Picking Fruit				
Flipping cards				
Flick letter tiles				
Avoiding spiders				
Swatting bats away				

**Video Recording Log Self-Gaming:**

In-Clinic Treatment Day:	Comments about recording (i.e. session completely recorded, battery died, etc.)
1	
2	
3	
4	

**Video Recording Log Tele-Gaming:**

In-Clinic/ Teleconsultation Treatment Day	Comments about recording (i.e. session completely recorded, battery died, etc.)
1 (clinic)	
2 (tele)	
3 (clinic)	
4 (tele)	
5 (clinic)	
6 (tele)	
7 (tele)	
8 (clinic)	
9 (tele)	
10 (tele)	

**MAL in Follow-up Recording Form for Tele-Gaming Group:**

<b>MAL Spreadsheet (How Well Scale Only)</b>	<b>F/U 1</b>	<b>F/U 2</b>	<b>F/U 3</b>	<b>F/U 4</b>
1. Turn on a light switch				
2. Open drawer				
3. Remove an item of clothing from a drawer				
4. Pick up phone				
5. Wipe off a kitchen counter or other surface				
6. Get out of car				
7. Open refrigerator				
8. Open a door by turning a door knob/handle				
9. Use a TV remote control				
10. Wash your hands (lathering and rinsing hands)				
11. Turning water on/off with knob/lever on faucet				
12. Dry your hands				
13. Put on your socks				
14. Take off your socks				
15. Put on your shoes				
16. Take off your shoes				
17. Get up from a chair with armrests				
18. Pull chair away from table before sitting down				
19. Pull chair toward table after sitting down				
20. Pick up a glass, bottle, drinking cup, or can				
21. Brush your teeth				
22. Use a key to unlock a door				
23. Carry an object in your hand				
24. Use a fork or spoon for eating				
25. Comb your hair				
26. Pick up a cup by a handle				
27. Button a shirt				
28. Eat half a sandwich or finger foods				
MEAN				

### Limb Activation Instructions (Pebble Watch):



- If the screen is showing the time, press “select”
- Toggle down to the app “Hands On”
- Push the select button to select the Hands On app (this is the limb activation)
- When you are using the device, make sure notifications are on (see above picture for how to turn them on/off)
- IMPORTANT: In order for the notifications to work (vibrate after 10 minutes of inactivity), you must click the “back” button and you will wear it with the time visible, not the amount of movements
- However, if you prefer to have the daily count visible, that is fine too, the notifications just will not work
- Wear the watch during all of your waking hours for the duration of your participation in the study
- The watch will need to be charged every night
  - The charger will insert into a USB on any computer and connect to the back of the watch
  - The display on the watch will say “charging” when it’s connected properly
- To reset the app, hold down the select button for a few seconds and release and everything will be set back to 0

**Pebble Watch Log:**

- Please record the daily count from your watch each night before you go to bed
- The first two days (baseline days) you will wear the watch on your unaffected arm, which will give you a goal for daily counts of your affected arm during the intervention

Date:	Baseline _____ —	Baseline _____ —	_____ —								
Daily Count:											

Date:	_____ _____ —											
Daily Count :												

## Treatment Materials – Usual Care

### **Traditional Rehabilitation Protocol**

#### **Guiding Principles:**

- Participants will receive the intervention on 4 visits that total 5 hours of participant/therapist contact. The 4 visits will be dispersed across the 3 weeks as evenly as possible. Ideally, the first 2 visits will occur during week 1 and the second 2 visits will be administered on weeks 2 and 3.
- The intervention will incorporate activities that are typically used in clinical settings for rehabilitation.
- The activities are designed to meet the specific needs of the participant (e.g., work to improve their body structure challenges, activity limitations, and participation goals).
- The protocol is standardized regarding activity categories, activity selection, activity intensity target level, and progression principles yet will be tailored to the participants' specific needs and goals.
- The amount of time dedicated to each activity category is specified below. It is expected that several trials of a given activity category may be accomplished during this time frame and it is expected that the number of trials may vary between participants based on their movement and endurance capabilities.
- For the active procedures of neuromuscular re-education, functional training, and progressive strengthening, the target for exercise intensity is 4 (somewhat hard) on the Borg CR10 Rating of Perceived Exertion Scale. Therapists should also assure that activities are conducted with high quality.
- When designing a clinical activity, therapists will select from a list of activities and grade the difficulty of the activity so that the participant is working at a level 4 on the Borg CR10 Rating of Exertion Scale. In subsequent visits, therapists should adjust the activity grade (up or down) to achieve that same level 4 of the Borg CR10 Scale.
- A home program will be designed for all participants on the first visit. This home program will consist of theraband strengthening exercises to be done over a 15 minute time period twice daily (total of 30 minutes each day) except on the days that they come into the laboratory for treatment. Therapists will design this program based on the participant's skill with the exercises and the appropriate level of exertion (4 on the Borg CR10 Scale). Therapists will provide written instructions on these exercise and will review and modify the exercise program, as appropriate, on subsequent clinic visits (i.e., visits 2-4).

**Allocation of treatment time** – The first treatment session will be 2 hours in length and subsequent treatment sessions will each be 1 hour in length.

Treatment Day 1

<b>Activity category</b>	Evaluate for therapeutic needs	Neuromuscular re-education	Functional Training	Progressive Strengthening	Establish and teach home program
<b>Time dedicated to this activity</b>	25 minutes	20 minutes	25 minutes	25 minutes	25 minutes

Other Treatment Days

<b>Activity category</b>	Review and adjust, as appropriate, home program	Neuromuscular re-education	Functional Training	Progressive Strengthening
<b>Time dedicated to this activity</b>	10 minutes	10 minutes	25 minutes	15 minutes

**Clinical Activity Description: Neuromuscular re-education (20 minutes TD1; 10 minutes TD2-4)**

Description: ICD definition: (ICD 97112)Neuromuscular re-education of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities Examples include: Biofeedback, PNF, manual facilitation, sensory priming.

These activities will be used to “prime” the motor responses and promote more coordinated and appropriate muscle responses during the functional training to follow.

**Clinical Activity Description: Functional Training (25 minutes all treatment days)**

Description: Functional training will focus around 4 categories of activities that have high relevance for functional use of the upper extremity (dexterity, interpersonal reaching, extrapersonal reaching, and overhead reaching). Each category of activities will be carried out for approximately 5 minutes, allowing another 5 minutes for switching between task categories. Participants will be seated for all activities and patients encouraged to keep their trunk against the back of the chair to promote proper posture. Assistive devices such as orthoses, taping or bandages can be used. Rest periods can be provided as much as needed.

1. Dexterity – Participants will use the more-affected hand to engage in various manipulation tasks for approximately 5 minutes of the functional training period during each of the treatment days. The specific manipulation task selected for that day will correspond with manipulation task in need of improvement for and preferred by that participant. The task should also be moderately challenging for that individual and leads to physical exertion rating of a 4 on the Borg CR10 Scale.  
Examples: picking up small objects (e.g., coins, paper clips, checkers) off of a table, buttoning a shirt, flipping playing cards.
2. Inter-personal Space Reaching – Participants will use the more-affected arm to engage in reaching and

manipulation tasks relatively close to their body (e.g., requiring less than 45 degrees of shoulder flexion). These tasks will be less likely to involve a great deal of trunk rotation and/or reaching across midline.

Examples: using a spoon to move beans from one bowl to another, moving a belt through belt loops, moving ping pong balls from one container to another.

3. Extra-personal Space Reaching – Participants will use the more-affected arm to engage in reaching and manipulation tasks relatively far away from their body (e.g., requiring between 45 and 90 degrees of shoulder flexion and approaching full extension of the elbow). These tasks will be more likely to involve trunk rotation and reaching across midline.

Examples: wiping off a counter, setting a table with eating utensils.

Overhead Reaching - Participants will use the more-affected arm to engage in reaching tasks toward a target that is held by a therapist and placed overhead (e.g., requiring greater than 90 degrees shoulder flexion and approaching full extension of the elbow).

Examples: combing hair with a brush, blow drying hair, putting a hat on/off, placing objects on a high shelf.

#### **Clinical Activity Description: Progressive Strengthening Activities (25 minutes TD1; 15 minutes TD 2-4)**

Description: Strengthening should emphasize shoulder flexion, Shoulder Abduction (with elbow extension or 90° of flexion), Shoulder Extension (with elbow extension or 90° of flexion), and Shoulder External Rotation (90° elbow flexion). Each movement will be carried out according to the description taken from the GRASP exercise program with no theraband or with the color of theraband providing the level of resistance corresponding to a level 4 on the Borg CR10 Scale and that allows good quality of movement. During the session, therapists will select a number of repetitions that correspond to moderate exertion (rating of 4 on the CR10 exertion scale) and will assign that number of repetitions for the home exercise program to be carried out until the next visit. The number of repetitions will be progressed as appropriate for that patient and corresponding with strength gains while maintaining Borg level 4 and completing the program in 30 minutes.

## Borg CR10 Rating of Perceived Exertion Scale

---

Rating	Description
0	Nothing at all
0.5	Very, very light
1	Very light
2	Fairly light
3	Moderate
4	Somewhat hard
5	Hard
6	
7	Very hard
8	

## **Traditional Therapy Checklist (Group 4)**

Note: Bolded items are separate sheets within the treatment packet to be completed

### **Prior to Treatment (after pre-test)**

1. Provide the activity monitors to participants and demonstrate use.
2. Instruct them to wear the activity monitors on both arms for 2 days before treatment to establish a baseline of arm use.
3. Make sure the participant knows to charge them overnight every night.

### **Treatment Day 1 (TD 1)**

1. Turn video camera on & say participant ID, treatment day, and group
2. Complete **Treatment Received Form**
3. 30 minutes of evaluation of affected upper extremity function.
4. 20 minutes of neuromuscular re-education. Complete **Treatment Log** Day 1.
5. 25 minutes of functional training. Complete **Treatment Log** Day 1.
6. 25 minutes of progressive strengthening. Complete **Treatment Log** Day 1.
7. 20 minutes of teaching home program. Complete **Treatment Log** Day 1.
8. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be.
9. Turn video camera off and add comments to **Therapist Treatment Recording Log**
10. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Treatment Day 2 (TD 2)**

1. Turn video camera on & say participant ID, treatment day, and group
2. 10 minutes of neuromuscular re-education. Complete **Treatment Log** Day 2.
3. 25 minutes of functional training. Complete **Treatment Log** Day 2.
4. 15 minutes of progressive strengthening. Complete **Treatment Log** Day 2.
5. 10 minutes of reviewing and updating home program. Complete **Treatment Log** Day 2.
6. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be.
7. Turn video camera off and add comments to **Therapist Treatment Recording Log**
8. Store the video on the encrypted hard drive under the correct group and session subfolder

### **Treatment Day 3 (TD 3)**

1. Turn video camera on & say participant ID, treatment day, and group
2. 10 minutes of neuromuscular re-education. Complete **Treatment Log** Day 3.
3. 25 minutes of functional training. Complete **Treatment Log** Day 3.
4. 15 minutes of progressive strengthening. Complete **Treatment Log** Day 3.
5. 10 minutes of reviewing and updating home program. Complete **Treatment Log** Day 3.
6. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be.
7. Turn video camera off and add comments to **Therapist Treatment Recording Log**
8. Store the video on the encrypted hard drive under the correct group and session subfolder

#### **Treatment Day 4 (TD 4)**

1. Turn video camera on & say participant ID, treatment day, and group
2. 10 minutes of neuromuscular re-education. Complete **Treatment Log** Day 4.
3. 25 minutes of functional training. Complete **Treatment Log** Day 4.
4. 15 minutes of progressive strengthening. Complete **Treatment Log** Day 4.
5. 10 minutes of reviewing and updating home program. Complete **Treatment Log** Day 4.
6. Ask participant about adverse events and fill out **Adverse Event Reporting Form** if need be.
7. Turn video camera off and add comments to **Therapist Treatment Recording Log**
8. Store the video on the encrypted hard drive under the correct group and session subfolder

**Video Recording Log** is the same as for the Self-Gaming Group.

**Usual Care Treatment Log**

	<b>TREATMENT DAY 1 (2 hours) Date: _____</b>	<b>TREATMENT DAY 2 (1 hour) Date: _____</b>	<b>TREATMENT DAY 3 (1 hour) Date: _____</b>	<b>TREATMENT DAY 4 (1 hour) Date: _____</b>		
<b>Evaluation</b>	(30 minutes)	N/A	N/A	N/A		
<b>Neuromuscular re-education</b>	(20 minutes) Level: Activities completed:	Intensity easy moderate hard	(10 minutes) Level: Activities completed:	Intensity easy moderate hard	(10 minutes) Level: Activities completed:	Intensity easy moderate hard
<b>Functional Training (one of each: dexterous, reaching close, far, high as possible)</b>	(25 minutes) Activities completed: 1. 2. 3. 4.	Intensity easy moderate hard	(25 minutes) Activities completed:	Intensity easy moderate hard	(25 minutes) Activities completed:	Intensity easy moderate hard
<b>Progressive Strengthening</b>	(25 minutes) Activities completed:	Intensity easy Moderate hard	(15 minutes) Activities completed:	Intensity easy moderate hard	(15 minutes) Activities completed:	Intensity easy moderate hard
<b>Teach, review home program (Shoulder strengthening Theraband GRASP, Pang, 2006</b>	flexion abduction extension external rotation (progress resistance of band and increasing repetitions as appropriate targeting 30 min of exercise at Borg level 4).	(20 minutes)	(10 minutes) Review and update HEP	(10 minutes) Review and update HEP	(10 minutes) Review and update HEP	(10 minutes) Review and update HEP

## Assessment Measures

### WOLF MOTOR FUNCTION TEST DATA COLLECTION FORM

Participant ID: \_\_\_\_\_ Date: \_\_\_\_\_ Site: \_\_\_\_\_

Test (check one): Pre-treatment \_\_\_\_\_ Post-treatment \_\_\_\_\_ 6 month follow-up \_\_\_\_\_

Affected arm (circle one): Right    Left

Task	Unaffected Arm Time (min:sec)	Affected Arm Time (min:sec)
1. Forearm to table (side)	_____	_____
2. Forearm to box (side)	_____	_____
3. Extend Elbow (side)	_____	_____
4. Extend Elbow (weight)	_____	_____
5. Hand to table (front)	_____	_____
6. Hand to box (front)	_____	_____
7. Weight to box	_____ lbs.	_____ lbs.
8. Reach and retrieve	_____	_____
9. Lift can	_____	_____
10. Lift pencil	_____	_____
11. Lift paper clip	_____	_____
12. Stack checkers	_____	_____
13. Flip cards	_____	_____
14. Grip strength	_____ kgs, _____ kgs, _____ kgs.	_____ kgs, _____ kgs, _____ kgs.
15. Turn key in lock	_____	_____
16. Fold towel	_____	_____
17. Lift basket	_____	_____

## Motor Activity Log (UE MAL) Score Sheet

### Amount Scale    How Well Scale

- |   |       |       |  |
|---|-------|-------|--|
| 1. Turn on a light with a light switch  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 2. Open drawer  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 3. Remove an item of clothing from a drawer   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 4. Pick up phone  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 5. Wipe off a kitchen counter or other surface  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 6. Get out of a car<br><i>(includes only the movement needed to get body from sitting to standing outside of the car, once the door is open).</i> | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 7. Open refrigerator  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 8. Open a door by turning a door knob/handle  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 9. Use a TV remote control  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 10. Wash your hands<br><i>( includes lathering and rinsing hands; does not include turning water on and off with a faucet handle).</i>            | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |

**Codes for recording “no” responses:**

1. “I used the unaffected arm entirely.” (assign “0”).
2. “Someone else did it for me.” (assign “0”).
3. “I never do that activity, with or without help from someone else because it is impossible.” For example, combing hair for people who are bald. (assign “N/A” and drop from list of items).
4. “I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.” (carry-over last assigned number for that activity).
5. Non-dominant hand hemiparesis. (only applicable to #24; assign “N/A” and drop from list of items).

**Amount Scale   How Well Scale**

- |   |       |       |  |
|---|-------|-------|--|
| 11. Turning water on/off<br>with knob/lever on faucet   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 12. Dry your hands  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 13. Put on your socks   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 14. Take off your socks   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 15. Put on your shoes<br><i>(includes tying shoestrings and fastening straps)</i>                   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 16. Take off your shoes<br><i>(includes untying shoestrings and unfastening straps)</i>             | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 17. Get up from a chair<br>with armrests  | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 18. Pull chair away from<br>table before sitting down   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 19. Pull chair toward table<br>after sitting down   | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |
| 20. Pick up a glass, bottle,<br>drinking cup, or can <i>(does not need<br/>to include drinking)</i> | _____ | _____ | if no, why? (use code) _____<br>Comments _____ |

**Codes for recording “no” responses:**

1. “I used the unaffected arm entirely.” (assign “0”).
2. “Someone else did it for me.” (assign “0”).
3. “I never do that activity, with or without help from someone else because it is impossible.” For example, combing hair for people who are bald. (assign “N/A” and drop from list of items).
4. “I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.” (carry-over last assigned number for that activity).
5. Non-dominant hand hemiparesis. (only applicable to #24; assign “N/A” and drop from list of items).

**Amount Scale   How Well Scale**

- |  |              |              |   |
|--|--------------|--------------|---|
| <p>21. Brush your teeth _____</p> <p><i>(does not include preparation of toothbrush or brushing dentures unless the dentures are brushed while left in the mouth)</i></p>                | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>22. Put on makeup base, lotion, or shaving cream on face _____</p>  | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>23. Use a key to unlock a door _____</p>  | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>24. Write on paper _____</p> <p><i>(If hand used to write pre-stroke is more affected, score item; if non-writing hand pre-stroke is more affected, drop item and assign N/A)</i></p> | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>25. Carry an object in your hand <i>(draping an item over the arm is not acceptable)</i> _____</p>  | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>26. Use a fork or spoon for eating <i>(refers to the action of bringing food to the mouth with fork or spoon)</i> _____</p>   | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>27. Comb your hair _____</p>  | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>28. Pick up a cup by a handle _____</p>   | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>29. Button a shirt _____</p>  | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |
| <p>30. Eat half a sandwich or finger foods _____</p>   | <p>_____</p> | <p>_____</p> | <p>if no, why? (use code) _____</p> <p>Comments _____</p> |

**Codes for recording “no” responses:**

1. “I used the unaffected arm entirely.” (assign “0”).
2. “Someone else did it for me.” (assign “0”).
3. “I never do that activity, with or without help from someone else because it is impossible.” For example, combing hair for people who are bald. (assign “N/A” and drop from list of items).
4. “I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.” (carry-over last assigned number for that activity).
5. Non-dominant hand hemiparesis. (only applicable to #24; assign “N/A” and drop from list of items).

## **Reasons for non-use**

1 – I used the unaffected arm entirely

2 – Someone else did it for me

3 – I never do that activity, with or without the help of someone else

4 – I sometimes do that activity, but did not have the opportunity since the last time I answered these questions

5 – Other

## **How Well Scale**

0 – The weaker arm was not used at all for that activity

**(never)**

1 – The weaker arm was moved during that activity, but was not helpful

**(very poor)**

2 – The weaker arm was of some use during that activity, but needed some help from the stronger arm, moved very slowly, or with difficulty

**(poor)**

3 – The weaker arm was used for the purpose indicated, but the movements were slow or were made only with some effort

**(fair)**

4 – The movements made by the weaker arm were almost normal, but not quite as fast or accurate as normal

**(almost normal)**

5 – The ability to use the weaker arm for that activity was as well as before the stroke

**(normal)**

## **Treatment Received Form**

Participant ID: \_\_\_\_\_

Please indicate the treatment you have received targeting your affected upper extremity prior to enrolling in this research study (check all that apply):

- Inpatient Rehabilitation
  - Outpatient Rehabilitation
  - Botox
  - Baclofen pump
  - Other research studies
  - Other:
-

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_  
Testing Session: \_\_\_\_\_  
Affected Hand (circle one): Right  
Left

### 9 HOLE PEG TEST

#### Directions for Participant:

*“You are going to take the pegs from the container, one by one, and place them into the holes on the board, as quickly as possible. You must then remove the pegs from the holes, one by one, and replace them back in the container. You may use the hand not being tested to hold the edge of the container to provide stability. You will have 120 seconds to complete this task. Do you have any questions?”*

#### Notes to tester:

- Test should be administered to both hands, starting with the unaffected hand
- The board should be placed at the participant’s midline
- Participant is allowed up to 120 seconds to complete the task
- Document the number of pegs placed and the total time per hand
- If the participant cannot complete the activity, number of pegs placed should be documented as 0 and total time should be documented as 120+

\_\_\_\_\_ *UNAFFECTED HAND* \_\_\_\_\_ *AFFECTED HAND* \_\_\_\_\_

**Number of pegs placed:** \_\_\_\_\_

**Number of pegs placed:** \_\_\_\_\_

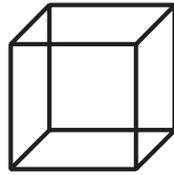
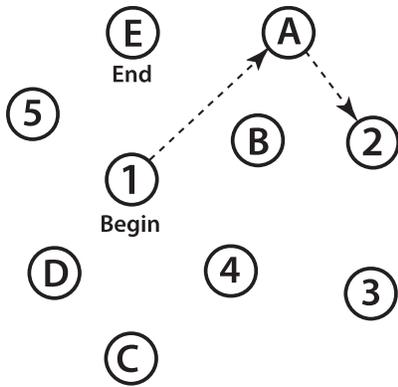
**Total Time (min:sec):** \_\_\_\_\_

**Total Time (min:sec):** \_\_\_\_\_

**MONTREAL COGNITIVE ASSESSMENT (MOCA)**

NAME : \_\_\_\_\_  
 Education : \_\_\_\_\_ Date of birth : \_\_\_\_\_  
 Sex : \_\_\_\_\_ DATE : \_\_\_\_\_

**VISUOSPATIAL / EXECUTIVE**



Copy cube

Draw CLOCK (Ten past eleven)  
(3 points)

POINTS

[ ]

[ ]

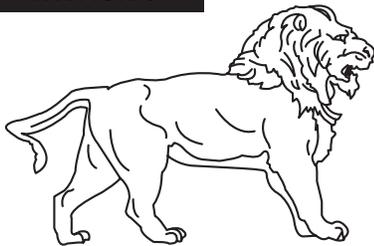
[ ]  
Contour

[ ]  
Numbers

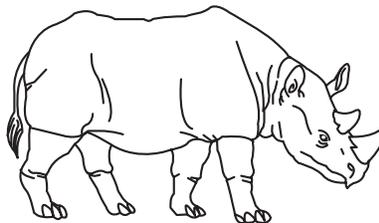
[ ]  
Hands

\_\_\_/5

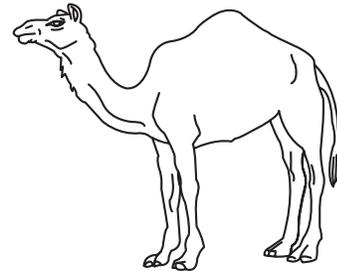
**NAMING**



[ ]



[ ]



[ ]

\_\_\_/3

**MEMORY**

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

**ATTENTION**

Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order

[ ] 2 1 8 5 4

Subject has to repeat them in the backward order

[ ] 7 4 2

\_\_\_/2

Read list of letters. The subject must tap with his hand at each letter A. No points if  $\geq 2$  errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

\_\_\_/1

Serial 7 subtraction starting at 100

[ ] 93

[ ] 86

[ ] 79

[ ] 72

[ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

\_\_\_/3

**LANGUAGE**

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

\_\_\_/2

Fluency / Name maximum number of words in one minute that begin with the letter F

[ ] \_\_\_\_\_ (N  $\geq$  11 words)

\_\_\_/1

**ABSTRACTION**

Similarity between e.g. banana - orange = fruit [ ] train - bicycle [ ] watch - ruler

\_\_\_/2

**DELAYED RECALL**

Has to recall words

FACE

VELVET

CHURCH

DAISY

RED

Points for UNCUED recall only

WITH NO CUE

[ ]

[ ]

[ ]

[ ]

[ ]

\_\_\_/5

**Optional**

Category cue

Multiple choice cue

**ORIENTATION**

[ ] Date

[ ] Month

[ ] Year

[ ] Day

[ ] Place

[ ] City

\_\_\_/6

Participant ID: \_\_\_\_\_

Date: \_\_\_\_\_

Testing Session: \_\_\_\_\_

Affected Hand (circle one): Left Right

### Modified ladder method: Touch-test sensory evaluator

Product Number	Evaluator Size	Target Force in grams	Representation	Palmar Hand & Dorsal Foot Thresholds	Plantar Thresholds
NC12775-01	1.65	0.1818	Green	Normal	Normal
NC12775-02	2.36	0.02			
NC12775-03	2.44	0.04			
NC12775-04	2.83	0.07			
NC12775-05	3.22	0.16	Blue	Diminished Light Touch	
NC12775-06	3.61	0.4			
NC12775-07	3.84	0.6	Purple	Diminished Protective Sensation	Diminished Light Touch
NC12775-08	4.08	1			
NC12775-09	4.17	1.1			
NC12775-10	4.31	2			
NC12775-11	4.56	4	Red	Loss of Protective Sensation	Diminished Protective Sensation
NC12775-12	4.71	6			
NC12775-13	4.93	8			
NC12775-14	5.07	10			
NC12775-15	5.18	15			
NC12775-16	5.46	26			
NC12775-17	5.88	60			
NC12775-18	6.10	100			
NC12775-19	6.45	180			
NC12775-20	6.65	300			

Start at 4.31 work up or down in sequence, record lowest level detected with three consecutive accurate responses:

Index finger R: \_\_\_\_\_

Index finger L: \_\_\_\_\_

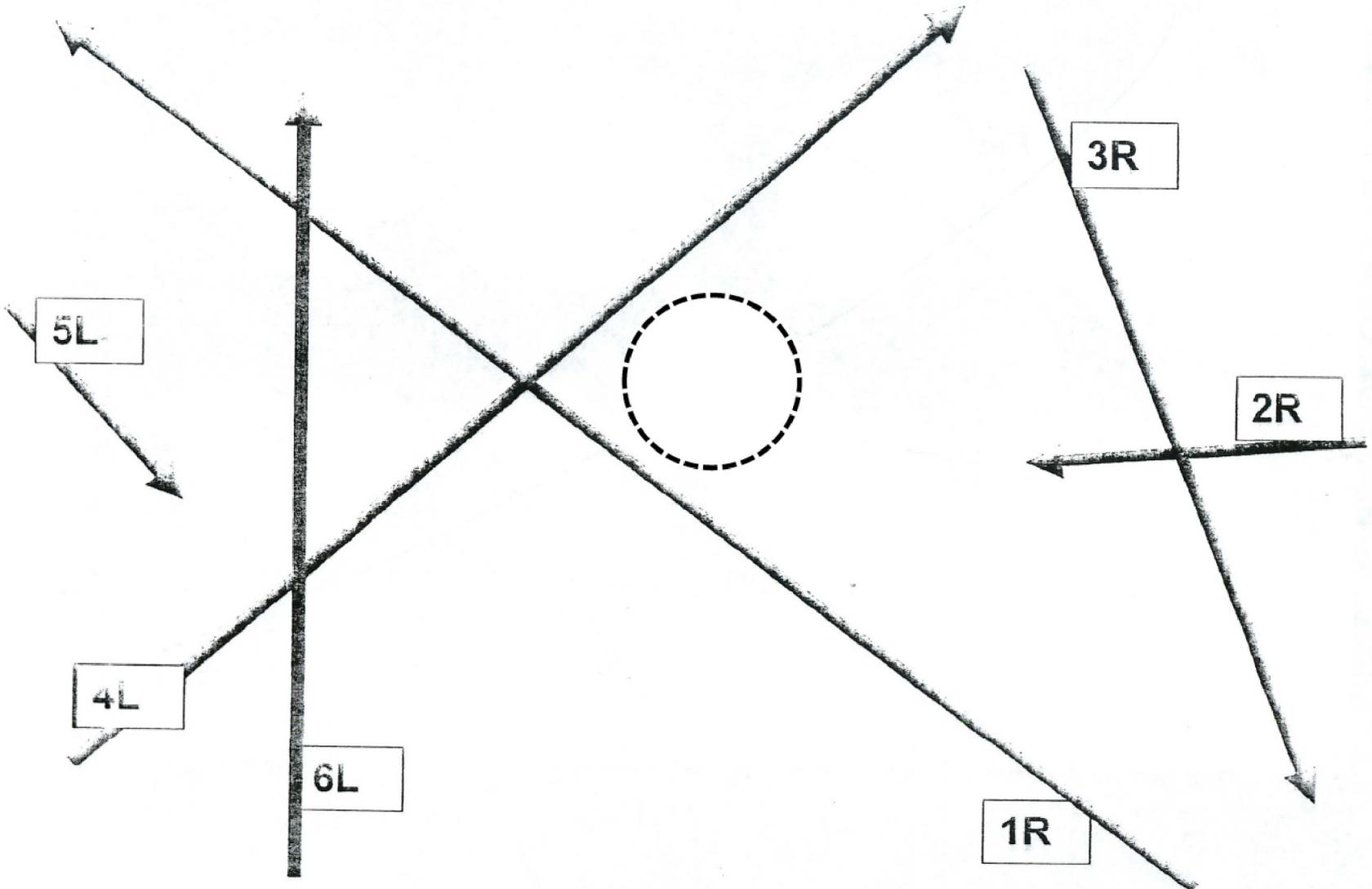
# BRIEF KINESTHESIA TEST

Motor Qualifier: Participants must be able to touch and hold for 3 seconds the center circle using vision to qualify to perform this measure. If unable, test only unaffected side.

Participant #: \_\_\_\_\_ Date: \_\_\_\_\_

Testing Session: \_\_\_\_\_

Affected Side (circle one): Left    Right



**Demographic Information**

Subject #: \_\_\_\_\_

Current date: \_\_\_\_\_

Date of Stroke: \_\_\_\_\_ (stroke that resulted in hemiparesis if more than 1 stroke)

Birthdate: \_\_\_\_\_

Handedness prior to stroke: Right Left Ambidextrous

More affected side: Right Left

Etiology: Ischemic Hemorrhagic Unknown

Race/ethnicity: \_\_\_\_\_

Gender: Male Female Other

Years Education (e.g., H.S.=12; college degree = 16): \_\_\_\_\_

Who lives with you? (circle all that apply):

Spouse Child(ren) Adult Child(ren) Caregiver Parent(s)

---

OSU RESEARCH STAFF ONLY BELOW THIS LINE

Rural: Yes No

SES:

**Therapist Observations to be collected on LAST day of treatment:**

**Involvement of Caregiver (check one):**

\_\_\_\_\_ 0 – Limited caregiver support (caregiver not present, did not engage in treatment, or doesn't help much at home)

\_\_\_\_\_ 1 – Supportive caregiver (s) – assists when appropriate and encourages independence when possible

\_\_\_\_\_ 2 – Enabling caregiver(s) – assists too frequently

**Level of Emotional Support in Family Environment (check one):**

\_\_\_\_\_ 0 – little emotional support or frequent interpersonal conflict

\_\_\_\_\_ 1 – more supportive than not

